

**IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

CLINTON COUNTY BOARD OF  
COMMISSIONERS,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE  
PHARMA, INC.; THE PURDUE  
FREDERICK COMPANY, INC.; TEVA  
PHARMACEUTICAL INDUSTRIES, LTD.;  
TEVA PHARMACEUTICALS USA, INC.;  
CEPHALON, INC.; JOHNSON & JOHNSON;  
JANSSEN PHARMACEUTICALS, INC.;  
ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC. n/k/a JANSSEN  
PHARMACEUTICALS, INC.; JANSSEN  
PHARMACEUTICA INC. n/k/a JANSSEN  
PHARMACEUTICALS, INC.; ENDO  
HEALTH SOLUTIONS INC.; ENDO  
PHARMACEUTICALS, INC.; ALLERGAN  
PLC f/k/a ACTAVIS PLC; WATSON  
PHARMACEUTICALS, INC. n/k/a  
ACTAVIS, INC.; WATSON  
LABORATORIES, INC.; ACTAVIS LLC;  
ACTAVIS PHARMA, INC. f/k/a WATSON  
PHARMA, INC.; AMERISOURCEBERGEN  
DRUG CORPORATION; CARDINAL  
HEALTH, INC.; MCKESSON  
CORPORATION; AND DOES 1 THROUGH  
100, INCLUSIVE,

Defendants.

Case No. 2:17-cv-01117

**COMPLAINT**

**JURY TRIAL DEMANDED AND  
ENDORSED HEREON**

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Plaintiff, Clinton County Board of Commissioners,<sup>1</sup> upon personal knowledge as to its own acts and beliefs and upon information and belief as to all matters based upon the investigation of counsel, alleges as follows:

## **I. INTRODUCTION**

1. Manufacturer Defendants<sup>2</sup> misrepresented the health effects of long-term use of opioids. Distributor Defendants<sup>3</sup> failed to perform their obligations when shipping millions of opioids to Ohio citizens, including Clinton County's citizens in rates that far exceeded reasonable levels of consumption. Instead of acting responsibly, Defendants placed profits over health and safety. Manufacturer Defendants knew that doctors would rely on their statements, and the statements of their key opinion makers, when making treatment decisions, all the while providing misleading information with the intent of creating a boon in sales. Then, as part of the closed system of distribution, Distributor Defendants failed to report the marked increase in opioid use, thus creating the opioid epidemic that Clinton County and all of Ohio is currently facing.

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<sup>1</sup> For convenience, the Clinton County Board of Commissioners will be referred to as either "Clinton County," "the County," or "Plaintiff" throughout the Complaint. If departments or offices of Clinton County are referenced, each will be specifically delineated.

<sup>2</sup> When the term "Manufacturer Defendants" is used, it collectively refers to all of the following defendants: Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLC; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

<sup>3</sup> When the term "Distributor Defendants" is used, it collectively refers to all of the following defendants: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

2. Defendants<sup>4</sup> were initiating actors in unleashing a healthcare crisis that has had far-reaching financial, social, and public health consequences in Clinton County, in Ohio, and across the nation. Clinton County specifically has been harmed financially since the epidemic began and will continue to face economic hardship as a result for years into the future.

3. Manufacturer Defendants manufacture, market, and sell prescription opioids (hereinafter “opioids”), including brand-name drugs such as Oxycontin and Percocet, and generics such as oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (*e.g.*, back pain, migraines, and arthritis),<sup>5</sup> opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

4. However, by the late 1990s, and continuing today, each Manufacturer Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Manufacturer Defendants falsely and misleadingly, and contrary to the language of their drugs’ labels, (1) downplayed the serious risk of addiction; (2) promoted the concept of “pseudoaddiction,” which advocated that the signs of addiction be treated with more, not fewer opioids; (3) exaggerated the effectiveness

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<sup>4</sup> When the term “Defendants” is used, it collectively refers to both Manufacturer Defendants and Distributor Defendants. Otherwise, the terms “Manufacturer Defendants” or “Distributor Defendants” will be used.

<sup>5</sup> In this Complaint, “chronic pain” means non-cancer pain lasting three months or longer.

of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

Conversely, Manufacturer Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no good evidence to support Manufacturer Defendants’ claims.

5. Manufacturer Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly through their sales representatives and in speaker groups led by physicians that specifically recruited to market the message. Borrowing a page from Big Tobacco’s playbook, Manufacturer Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”). Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors have traditionally relied on for ostensibly “neutral” guidance, such as treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioid use.

6. Each Manufacturer Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence.

Indeed, the falsity of each Manufacturer Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlements agreements in other jurisdictions with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Still, each Manufacturer Defendant continues to misrepresent the risks and benefits of long-term opioid use in Ohio and continues to fail to correct its past misrepresentations.

7. Manufacturer Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."<sup>6</sup> This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply) and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids, heroin, or other related drugs such as fentanyl.

8. Much of the brunt of the epidemic could have been – and should have been – alleviated by the Distributor Defendants, who are the three major distributors of controlled

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<sup>6</sup> Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at <http://turnthetiderx.org/>.

substances. Each distributes prescription drugs closely identified with the prescription drug abuse problem in the County and nationwide. Defendants AmerisourceBergen, Cardinal Health, and McKesson are some of the largest corporations in America and together account for 85-90% of all revenues from drug distribution in the United States, estimated at \$378.4 billion in 2015.

9. Distributor Defendants are required to serve as a check in the drug delivery “closed” system by having an effective anti-diversion program that secures and monitors controlled substances at every step as they travel through commerce, including the specific requirements that Distributor Defendants refuse to fill suspicious or unusual orders by downstream pharmacies and report such suspicious orders to the authorities. By receiving a license to distribute such dangerously addictive controlled substances, Distributor Defendants must abide by these indispensable requirements in order to continue to have that right. But Distributor Defendants utterly failed in this duty; they have habitually turned a blind eye to known or knowable problems in their supply chains. This inexcusable blindness and abdication of responsibility has horrific consequences. As one ex-DEA supervisor, Joe Rannazzissi, explained on *60 Minutes*: “This is an industry that’s out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they [Drug Distributors] don’t follow the law in drug supply, people die. That’s just it. People die.”<sup>7</sup>

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<sup>7</sup> See <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/>



10. Unfortunately, Distributor Defendants abdicated their “check” obligation and acted negligently, recklessly, and intentionally in violation of Ohio and federal statutes and regulations governing controlled substances and drug supply as well as the common law. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74; Ohio Admin. Code §§ 4729-9-05(A), 4729-9-11, and 4729-9-16.

11. Recently, it has been well publicized in the media that Ohio has for years been one of the “most medicated” states in the Country, with a prescription drug abuse problem of epidemic proportions. Distributor Defendants were thus on notice of the growing epidemic of the abuse of the prescription drugs they supplied. Yet, Distributor Defendants supplied these addictive and frequently abused controlled substances to pharmacies that dispensed them in huge quantities, often based upon bogus prescriptions from physicians who were prescribing them for

illegitimate medical purposes. Distributor Defendants also filled orders from pharmacies for large and/or unusual quantities of frequently abused controlled substances rather than terminate the relationship with the pharmacy customer and report their suspicious orders to law enforcement.

12. Such breaches of their duties by the Distributor Defendants are a direct and proximate cause of the widespread diversion of prescription drugs for non-medical purposes, the consequent prescription drug epidemic, and the damages those have wrought.

13. Distributor Defendants supplied the indispensable fuel to the conflagration that is ravaging communities such as the County. That is, Distributor Defendants created conditions that allowed massive amounts of controlled substances to be diverted from legitimate channels of distribution into the illicit market and otherwise flow freely from manufacturers to end user abusers in quantities that fueled the opioid epidemic in the County and elsewhere. Acting in violation of their aforesaid common law and statutory duties, Defendants created an environment in which such drug diversion flourished, largely by its over-supply to unscrupulous pharmacies. As a result, users of controlled substances in and around the County have and had ready access to illicit controlled substances that had no legitimate medical purposes. This availability and accessibility of dangerously addictive controlled substances led to addiction and abuse.

14. This diversion and the consequent epidemic are direct harms for which Plaintiff seeks to recover from Distributor Defendants. The County's damages are further articulated below.

15. For years, Distributor Defendants and their agents had the ability to substantially reduce the death toll and adverse economic consequences of the prescription drug epidemic in the County and elsewhere, including the deaths of hundreds of County citizens and gargantuan

expenditures by the County in dealing with the problem – but Distributor Defendants instead profited greatly and pursued even more revenue.

16. As a result of the conduct of Manufacturer Defendants and Distributor Defendants, opioids have engulfed Clinton County and the state of Ohio in a public health crisis the likes of which has never been seen. In 2012, the total number of opioid doses prescribed to Ohio patients soared to 793 million – enough to supply every man, woman, and child in the state with **68 pills each**.<sup>8</sup> In 2016 alone, 2.3 million Ohio patients – roughly 20% of the state’s population – were prescribed an opioid drug.<sup>9</sup>

17. Defendants’ actions have caused a dangerous oversupply of opioids to Clinton County. For example, 94.8 opioid pills were distributed per person in Clinton County in 2010. In 2011, the per capita distribution equaled 97.2 pills, followed by 96.0, 91.7, and 85.1 pills per person in the years 2012, 2013, and 2014, respectively. Even as of 2015, an astounding 81.2 pills were distributed for every man, woman, and child in Clinton County, 20 higher than the state average.

18. Defendants’ actions have caused an opioid crisis that presents catastrophic results. Opioids have become the main source of unintentional drug overdose in the state of Ohio and, due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in recent years.<sup>10</sup> 2016 saw a 36% increase in unintentional fatal overdoses in the state of Ohio from the previous year, when Ohio led the nation in the total

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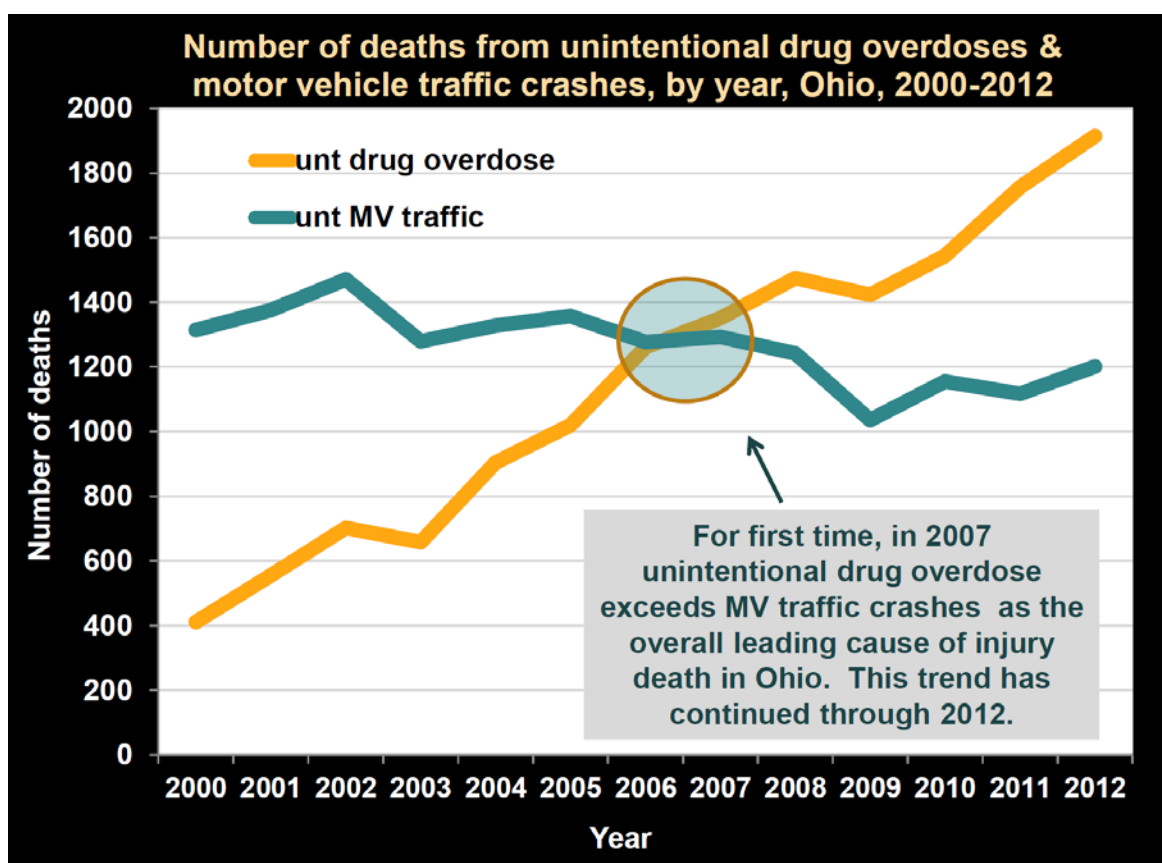
<sup>8</sup> Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010; Ohio Opiate Action Team, Fighting Prescription Drug Abuse, Rx Prescribing Guidelines; Ohio Automated RX Reporting System, 2016 Annual Report. OARRS tracks only legitimately-prescribed drugs and does not track illegal use.

<sup>9</sup> Ohio Automated RX Reporting System, 2016 Annual Report.

<sup>10</sup> Ohio Department of Health, 2015 Ohio Drug Overdose Data General Findings.

number of fatal overdoses.<sup>11</sup> This total is expected to go higher as coroners in six smaller counties update their numbers.<sup>12</sup>

19. Unintentional drug-related overdoses surpassed car accidents as the leading cause of accidental death in Ohio in 2007, so city and county health commissioners in Ohio declared a public health emergency in January 2010 based upon the growing number of fatalities.<sup>13</sup> Since that time, numerous Ohio counties have followed suit. Nevertheless, overdose rates have continued to grow.



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<sup>11</sup> Newspaper: *Ohio had more than 4,000 overdose deaths in 2016* (May 28, 2017), available at: <http://www.dispatch.com/news/20170528/newspaper-ohio-had-more-than-4000-overdose-deaths-in-2016>.

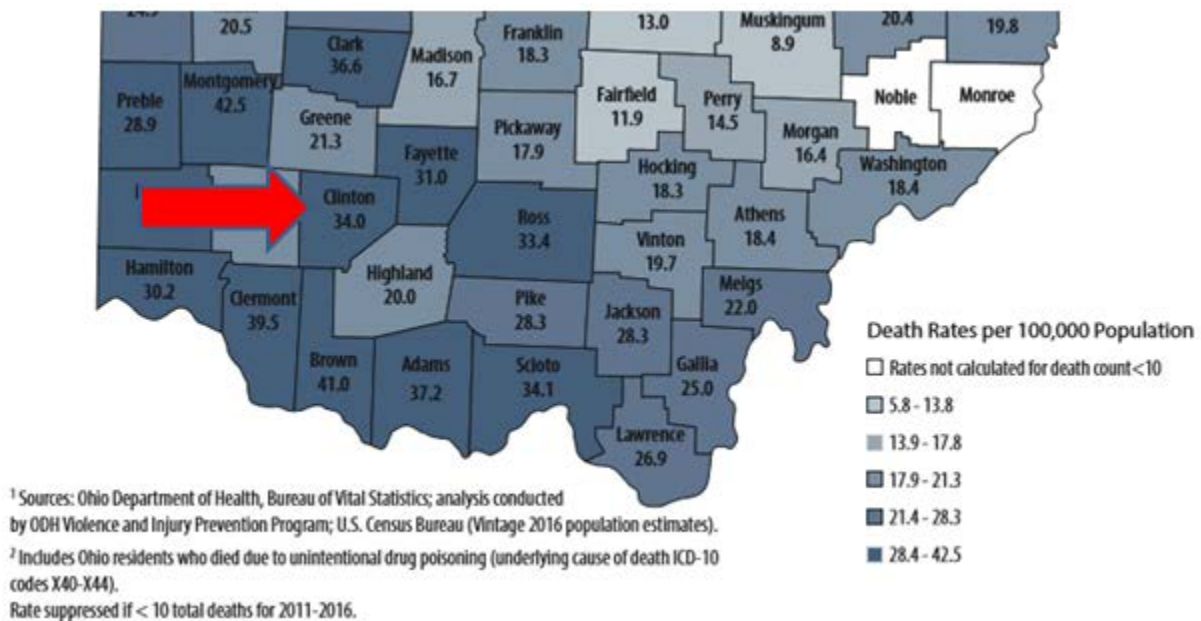
<sup>12</sup> *Id.*

<sup>13</sup> Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

<sup>14</sup> Ohio Department of Health, *Ohio's Opioid Epidemic: An Overview of the Problem*; see also ODH Office of Vital Statistics.

20. In Clinton County, the statistics are no better on unintentional overdose deaths. Statistics compiled in 2016 indicate that there were 3 overdose deaths in 2010, 6 in 2011, 13 in 2012, 16 in 2013, and 13 in 2014. In only the first six months of 2015, Clinton County faced 9 overdose deaths; by the end of the year, there had been 20 overdose deaths.

21. The Ohio Department of Health has indicated that the 2011-2016 overdose death rate per 100,000 population for Clinton County is 34.0, a number that significantly exceeds most of Ohio's other counties.



22. The Ohio Department of Health's 2016 Ohio Drug Overdose Data: General Findings indicates that Clinton County has the ninth-highest age-adjusted rate of overdose deaths per 100,000 population.

County	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2011-2016 Total	Crude Rate	Age Adjusted Rate
MONTGOMERY	127	116	125	130	145	121	113	119	150	199	251	239	320	1,278	40.0	42.5
BROWN	8	5	5	10	12	13	17	11	14	17	17	23	18	100	37.7	41.0
BUTLER	21	31	47	45	55	68	59	80	92	120	151	195	211	849	37.9	40.5
CLERMONT	25	22	31	36	38	32	49	49	56	65	80	105	96	451	37.5	39.5
ADAMS	1	6	6	5	6	10	6	6	10	6	10	12	12	56	33.1	37.2
CLARK	25	15	18	20	19	19	19	34	36	28	38	71	73	280	34.2	36.6
TRUMBULL	38	29	30	58	41	43	43	57	34	37	54	89	111	382	31.0	34.2
SCIOTO	14	17	15	19	20	24	22	25	17	18	23	30	35	148	31.8	34.1
CLINTON	12	4	6	8	10	11	3	6	13	16	13	20	12	80	31.8	34.0
OHIO TOTAL	904	1,020	1,261	1,351	1,473	1,423	1,544	1,772	1,914	2,110	2,531	3,050	4,050	15,427	22.2	23.1

23. The effect of the opioid crisis on families in Clinton County has been devastating, and the consequences for the County's children services program are significant. The opioid crisis has been reported as creating an increase in the number of children in the custody and care of Clinton County Job and Family Services, resulting in a need for an additional \$1,000,000.00 needed through the end of 2018.<sup>15</sup> This budget crisis is "due largely to an increase in foster care placement costs," not operational costs, with "[t]he opiate scourge afflicting the county [having] led to an increased need to place children of drug-addicted parents in foster care."<sup>16</sup>

24. In 2013, 35% of the case opened by the County's Child Protective Unit had drug involvement.

25. In 2015, 71% of the County's Child Protective Unit's child abuse and neglect cases included drug addiction.

<sup>15</sup> Gary Hufferberger, *Clinton County's Foster Care Levels Keep on Rising*, WILMINGTON NEWS JOURNAL (Oct. 11, 2017), <http://www.wnewsj.com/news/52871/clinton-countys-foster-care-levels-keep-on-rising>

<sup>16</sup> *Id.*

26. But even these alarming statistics do not fully describe the toll of prescription opioid abuse on patients and their families, as the dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long term dependence on opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

27. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on state and county agencies that address heroin use and addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive (especially when covered by insurance), readily available alternative that provides a similar high.<sup>17</sup>

28. An estimated 1,162,000 Ohio citizens suffer from chronic pain,<sup>18</sup> which takes an enormous toll on their health, lives, and families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Manufacturer Defendants' deceptive marketing campaign deprived Ohio patients and their doctors of the ability to make informed medical decisions. Instead, they caused important, sometimes life-or-death decisions to be made on hype rather than science. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

29. Manufacturer and Distributor Defendants' conduct has also exacted, and foreseeably so, a financial burden on Clinton County, Ohio. Clinton County has incurred more

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<sup>17</sup> Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

<sup>18</sup> Report of the Ohio Compassionate Care Task Force (Mar. 2004).

law enforcement costs, including, but not limited to, additional patrols to deal with the attendant crime and cost of expensive medication necessary to reverse the effects of overdoses. Clinton County has incurred additional costs of jailing opioid-related offenders and necessary treatment for them while incarcerated. Clinton County has also faced drastically increased expenses for child care and foster placement stemming from the opioid epidemic.

30. To redress and punish these violations of law, Clinton County, by and through the Clinton County Board of Commissioners, seeks damages for the above-referenced costs incurred and all others identified through discovery and proved at trial. Clinton County also seeks a declaration that Defendants' conduct has violated Ohio law, an order requiring Manufacturer Defendants to cease their unlawful promotion of opioids and correct their misrepresentations, an order requiring Distributor Defendants to comply with their state and federal duties, and an order requiring Defendants to abate the public nuisance they have created and knew their actions would create. Clinton County also seeks punitive damages, treble damages, and attorney's fees and costs, in addition to granting any other equitable relief authorized by law.

## **II. JURISDICTION AND VENUE**

31. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 based upon Clinton County's claims under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, *et seq.* Supplemental jurisdiction applies to Clinton County's state law claims, pursuant to 28 U.S.C. § 1367, because those claims are so related to Clinton County's federal claims that they constitute part of the same case or controversy.

32. This Court has personal jurisdiction over Defendants as they conduct business in Ohio, purposefully direct or directed their actions toward Ohio, and/or have the requisite minimum contacts with Ohio necessary to constitutionally permit the Court to exercise jurisdiction.

33. Venue is proper in this District under S.D. Ohio Civ. R. 82.1(c), which provides “[a]n action against a defendant or defendants resident in this District shall be filed at the location of Court that serves a county in which at least one defendant resides.” *See also* 28 U.S.C. § 1391(c). Defendant Cardinal Health, Inc. is an Ohio corporation with its principal office located in the City of Dublin in Franklin County, Ohio, which is located in the Eastern Division of the Southern District of Ohio and served by the Columbus location of Court. Venue is further proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. § 1965(a).

### **III. PARTIES**

#### **A. Plaintiff**

34. This action is brought for and on behalf of the CLINTON COUNTY BOARD OF COMMISSIONERS, who have standing to bring this lawsuit under Ohio Rev. Code § 305.12. As such, Clinton County brings this suit to recover all associated damages caused by Defendants’ actions, as alleged in this Complaint and to be further developed through discovery.

#### **B. Defendants**

35. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”).

36. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Ohio. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

37. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

38. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Ohio. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."<sup>19</sup> In 2008, Cephalon paid \$425 million when it pleaded guilty to a criminal violation of the Federal Food, Drug, and Cosmetic Act for its misleading promotion of Actiq and two other drugs.

39. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for

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<sup>19</sup> Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Clinton County and across Ohio, discloses that the guide was submitted by Teva USA and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Clinton County and across Ohio, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd. operates in Ohio and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are collectively referred to as “Cephalon”).

40. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of

JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen").

41. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Clinton County, including the opioid Duragesic. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

42. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo").

43. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydane, in the U.S. and Ohio, including Clinton

County. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Ohio, including Clinton County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

44. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

45. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Ohio, including Clinton County. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

46. AMERISOURCEBERGEN DRUG CORP. AmerisourceBergen Drug Corp. (“AmerisourceBergen”) is a publicly traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription drugs to providers and retailers in the County. AmerisourceBergen has purposefully availed itself of the advantages of conducting business with and within the County. AmerisourceBergen is listed as number 11 on *Forbes* Fortune 500 list, which is one spot ahead of Amazon.

47. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company headquartered in Ohio and incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription drugs to providers and retailers in the County. Cardinal has purposefully availed itself of the advantages of conducting business with and within the County. Cardinal is listed as number 15 on *Forbes* Fortune 500 list, which is one spot ahead of Costco.

48. McKESSON CORPORATION (“McKesson”) is a publicly traded company headquartered in San Francisco and incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription drugs to providers and retailers in the County. McKesson has purposefully availed itself of the advantages of

conducting business with and within the County. McKesson is listed as number 5 on the *Forbes* Fortune 500 list, which is one spot behind Exxon Mobil.

49. Clinton County currently lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Fed. R. Civ. P. 15(D). Clinton County will amend this Complaint to show their true names and capacities if and when they are ascertained. Clinton County is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

#### **IV. FACTUAL ALLEGATIONS REGARDING MANUFACTURER DEFENDANTS**

50. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, for pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

51. To take advantage of the lucrative market for chronic pain patients, each Manufacturer Defendant developed a well-funded marketing scheme based on deception. Each Manufacturer Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy when Manufacturer Defendants repeated those statements, but

also other opioid manufacturers. Yet these statements were not only unsupported by, or contrary to, the scientific evidence, they were also contrary to pronouncements by, and guidance from, the FDA and CDC. They also targeted susceptible prescribers and vulnerable patient populations.

**A. Manufacturer Defendants Used Multiple Avenues To Disseminate Their False And Deceptive Statements About Opioids.**

52. Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Clinton County and across Ohio. Manufacturer Defendants also deployed ostensibly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the county and the State.

**1. Manufacturer Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.**

53. Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

54. Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website [opana.com](http://opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with

osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Ohio.

55. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through “detailers” – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. These detailers consistently informed physicians that opioids were a medically appropriate and generally non-addicting treatment option for chronic pain. Manufacturer Defendants have not corrected this misinformation. Instead, each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Actavis.

56. Manufacturer Defendants’ detailers have been reprimanded for their deceptive promotions. A July 2010 “Dear Doctor” letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that “[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian],” including the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids” and, specifically, the risk that “[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.”

57. Manufacturer Defendants also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers and meals paid for by Manufacturer

Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

58. Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Manufacturer Defendants purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry, namely data available from IMS Health Holdings, Inc., to track-precisely-the rates of initial prescribing and renewal by individual doctor. Such data mining in turn allows them to target, tailor, and monitor the impact of their core messages. Manufacturer Defendants *know* their detailing to doctors is effective.

59. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in Ohio as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

60. Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

**2. Manufacturer Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.**

61. Manufacturer Defendants also deceptively marketed opioids in Clinton County and across Ohio through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Manufacturer Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

62. Manufacturer Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Manufacturer Defendants also used third-party, unbranded

advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

63. Manufacturer Defendants’ deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

<b>Pain: Opioid Therapy (Unbranded)</b>	<b>Opana ER Advertisement (Branded)</b>
<p>“People who take opioids <b>as prescribed usually do not become addicted.</b>”</p>	<p>“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since <b>use of opioid analgesic products carries the risk of addiction even under appropriate medical use.</b>”</p>

**a. Key Opinion Leaders (“KOLs”)**

64. Manufacturer Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as “key opinion leaders” or “KOLs.”

65. Manufacturer Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Manufacturer Defendants by advancing their marketing

goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

66. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Manufacturer Defendants created opportunities for KOLs to participate in research studies Manufacturer Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

67. Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

68. Pro-opioid doctors are one of the most important avenues that Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

69. Thus, even though some of Manufacturer Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the state of Ohio, including in Clinton County, in Manufacturer Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

70. Manufacturer Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

**(1) Russell Portenoy**

71. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and he was a paid consultant to Cephalon and Purdue.

72. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

73. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast in Ohio, including in Clinton County, and across the country, Dr. Portenoy claimed: "Addiction,

when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”<sup>20</sup>

74. To his credit, Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”<sup>21</sup> Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”<sup>22</sup>

**(2) Lynn Webster**

75. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr.

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<sup>20</sup> Good Morning America television broadcast, ABC News (Aug. 30, 2010).

<sup>21</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.

<sup>22</sup> *Id.*

Webster was receiving significant funding from Manufacturer Defendants (including nearly \$2 million from Cephalon).

76. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

77. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

78. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Ohio doctors.

79. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," which is the notion that addictive behaviors should be seen not as warnings but rather as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when

faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”<sup>23</sup>

**b. Front Groups**

80. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

81. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Manufacturer Defendants made sure that the Groups would generate only the messages Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

82. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there

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<sup>23</sup> John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), American Society of Pain Education (“ASPE”), National Pain Foundation (“NPF”), and Pain & Policy Studies Group (“PPSG”).

**(1) American Pain Foundation (“APF”)**

83. The most prominent of Manufacturer Defendants’ Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

84. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Ohioans.

85. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all served on APF’s Board and reviewed its publications. Another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

86. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

87. APF held itself out as an independent patient advocacy organization. It routinely engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

88. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

89. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

90. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

91. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturer Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow Defendants to control its activities and messages support an inference that each Manufacturer Defendant that worked with it was able to exercise editorial control over its publications.

92. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

## **(2) American Academy of Pain Medicine ("AAPM")**

93. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Manufacturer Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

94. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort location. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

95. AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”<sup>24</sup>

96. AAPM's staff understood they and their industry funders were engaged in a common task. Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

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<sup>24</sup> Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), <http://www.medscape.org/viewarticle/500829>.

97. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

98. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

99. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo, and Purdue.

100. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan

Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature and were disseminated in Ohio during the relevant time period. These Guidelines are still available online and were reprinted in the *Journal of Pain*.

101. Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

102. Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Manufacturer Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Manufacturer Defendants determined would reduce prescribing.

**B. Manufacturer Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.**

103. To convince doctors and patients in Clinton County and across Ohio that opioids can and should be used to treat chronic pain, Manufacturer Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving

those doctors and patients about the risks and benefits of long-term opioid use, Manufacturer Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Manufacturer Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

**1. Manufacturer Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.**

104. To convince doctors and patients that opioids are safe, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impressions that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

105. *First*, Manufacturer Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly. Manufacturer Defendants failed to disclose the greater risk of addiction with prolonged

use of opioids. Some illustrative examples of these false and deceptive claims are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website [www.opana.com](http://www.opana.com).
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

- h. Detailers for Purdue, Endo, Janssen, and Cephalon in Ohio minimized or omitted any discussion with doctors of the risk of addiction, misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations, and routinely failed to correct the misrepresentations noted above.

106. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

107. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

108. The warnings on Manufacturer Defendants’ own FDA-approved drug labels caution that opioids “expose[] users to risks of addiction, abuse and misuse, which can lead to

overdose and death,” that the drugs contain “a substance with a high potential for abuse,” and that addiction “can occur in patients appropriately prescribed” opioids.

109. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its [www.opana.com](http://www.opana.com) website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in Ohio, including in Clinton County.

110. **Second**, Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Manufacturer Defendants called this phenomenon “pseudoaddiction” – a term coined by Dr. J. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue. They falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

- b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

111. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

112. Not even one of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the State of New York, in its 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’” Consistent with this, Endo agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York. Endo, however, remains free to do so in Ohio, including in Clinton County.

113. **Third**, Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants’ misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.

- b. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths.”
- c. As recently as 2015, Purdue has represented in scientific conferences that “bad apple” patients – and not opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.

114. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

115. **Fourth**, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

116. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.

117. Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

118. ***Fifth***, Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

- a. Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated: “Over time, your body may become tolerant of

your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

- b. Cephalon and Purdue sponsored *APF’s Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.
- c. Endo sponsored a website, [painknowledge.com](http://painknowledge.com), which claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Purdue’s In the Face of Pain website promotes the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary,” even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.
- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,”<sup>25</sup> challenging the correlation between opioid dosage and overdose.

119. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states that “there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages.” That is why the CDC advises doctors to “avoid increasing dosages” above 90 morphine milligram equivalents per day.

120. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

121. **Finally**, Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.<sup>26</sup>

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<sup>25</sup> [www.cpdd.org](http://www.cpdd.org).

<sup>26</sup> Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

122. More specifically, Manufacturer Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

123. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

124. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Manufacturer Defendants successfully convinced doctors and patients to discount those risks.

**2. Manufacturer Defendants grossly overstated the benefits of chronic opioid therapy.**

125. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that

“[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials  $\leq$  6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.” Despite this, Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Manufacturer Defendants failed to correct these false and deceptive claims, they continue to make them today.

126. For example, Manufacturer Defendants falsely claimed that long-term opioid use improved patients’ function and quality of life. Some illustrative examples are described below:

- a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients’ function.

- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.
- g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- i. In 2009, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.
- j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.
- k. Sales representatives from Purdue, Cephalon, Endo, and Janssen have conveyed and continue to convey the message that opioids will improve patient function.

127. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . . .”
- “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

128. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

129. The 2016 CDC Guideline was not the first time a federal agency repudiated Manufacturer Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 40, that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s

work, physical and mental functioning, daily activities, or enjoyment of life.”<sup>27</sup> And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

130. Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

131. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue’s own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which the release tapers off. This

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<sup>27</sup> Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm’n, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm>.

triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial number” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period. As a result, people are driven to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

132. Purdue’s competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to “real” 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue’s sales representatives continue to tell Ohio doctors that OxyContin lasts a full 12 hours.

133. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleeps though the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.<sup>28</sup>

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<sup>28</sup> See Reply Br. of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, 2004 WL 1637768, at \*4.

**3. Manufacturer Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.**

134. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

135. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

- Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

136. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

137. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin. Notably, this is the same OxyContin that Purdue had promoted as less addictive in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin

tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

138. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

139. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

**C. Manufacturer Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.**

140. As a part of their deceptive marketing scheme, Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including in Clinton County. For example, Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Manufacturer Defendants' misrepresentations.

141. Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater

for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are “special risks of long-term opioid use for elderly patients” and recommends that doctors use “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

**D. Although Manufacturer Defendants Knew That Their Marketing Of Opioids Was False And Deceptive, They Fraudulently Concealed Their Misconduct.**

142. Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids are highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of this, and Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events-including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Manufacturer Defendants’ misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

143. Moreover, at all times relevant to this Complaint, Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, [painknowledge.org](http://painknowledge.org), which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

144. Finally, Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Clinton County or anyone else.

145. Thus, Manufacturer Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the County now asserts. The County did not know of the existence or scope of Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence

**E. By Increasing Opioid Prescriptions And Use, Manufacturer Defendants' Deceptive Marketing Scheme Has Fueled The Opioid Epidemic And Devastated Ohio Communities.**

146. Manufacturer Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.<sup>29</sup>

147. Manufacturer Defendants' deceptive marketing scheme caused and continues to cause doctors in Ohio to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Manufacturer Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Manufacturer Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Manufacturer Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

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<sup>29</sup> Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), available at <http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction>.

148. Manufacturer Defendants’ deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Manufacturer Defendants’ spending on their deceptive marketing scheme. Manufacturer Defendants’ spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

149. The escalating number of opioid prescriptions written by doctors who were deceived by Manufacturer Defendants’ deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Ohio, including in Clinton County. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”

150. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

151. Contrary to Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers, or the internet.<sup>30</sup> Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

152. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Ohio. Between 2011 and 2015, over **3.8 billion doses** of opioid medication were prescribed in Ohio alone.<sup>31</sup> In 2015, 85 percent of all accidental drug overdose deaths in the state were caused by an opioid.<sup>32</sup> It is unsurprising, given the widespread epidemic, that a recent poll found that 40% of adults in Ohio knew someone who had overdosed due to a prescription painkiller and 56% knew someone who had overdosed from heroin.<sup>33</sup>

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<sup>30</sup> See U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

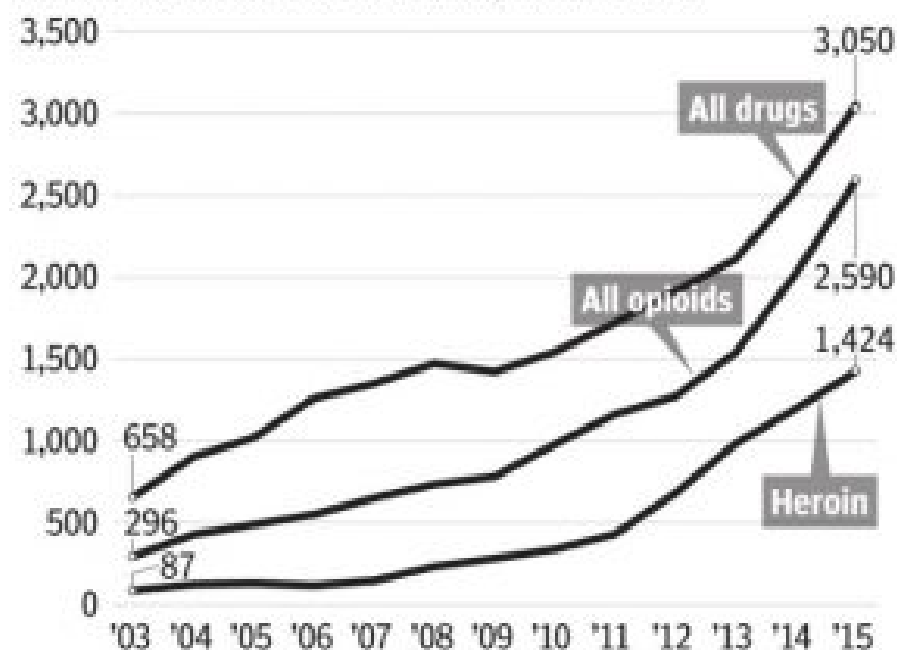
<sup>31</sup> 2015 Ohio Drug Overdose Data: General Findings; State of Ohio Board of Pharmacy, Ohio Automated Rx Reporting System.

<sup>32</sup> Ohio Department of Health, 2015 Ohio Drug Overdose Data General Findings; *see also* Governor's Cabinet Opiate Action Team, <http://fightingopiateabuse.ohio.gov/>.

<sup>33</sup> Ohio Health Issues Poll (April 2016). [https://www.interactforhealth.org/upl/Heroin\\_use\\_prescription\\_drug\\_misuse\\_still\\_climbing\\_in\\_Ohio.pdf](https://www.interactforhealth.org/upl/Heroin_use_prescription_drug_misuse_still_climbing_in_Ohio.pdf); Ohio Department of Health. (September 2015). 2014 Ohio Drug Overdose Preliminary Data: General Findings. Retrieved Oct. 22, 2015, from [www.healthy.ohio.gov/vipp/data/rxdata.aspx](http://www.healthy.ohio.gov/vipp/data/rxdata.aspx).

## Overdose deaths in Ohio

Overdose deaths caused by opioids, and specifically heroin, have risen dramatically since 2003.



\*Individual drugs do not add up to the total deaths because more than one drug was listed for the cause of death in some cases.

Source: Ohio Department of Health

GATEHOUSE MEDIA

153. When compared to previous drug overdose epidemics in Ohio, the current prescription drug epidemic is responsible for considerably more deaths. In 2010, mortality rates were 4 to 5 times higher than the rates during the “black tar” heroin epidemic in the mid-1970s and more than 3 times what they were during the peak years of the crack cocaine epidemic in the early 1990s.<sup>34</sup> From 2000 to 2015, drug overdose fatalities in Ohio increased by 642% – equating to 8 deaths per day or 1 death every 3 hours in 2015.<sup>35</sup> In 2014 and 2015, Ohio had the greatest number of deaths in the nation from synthetic opioids – with 1 in every 14 deaths from

<sup>34</sup> Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

<sup>35</sup> Ohio Department of Health, <https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx> (last visited May 12, 2017).

synthetic opioids in the United States occurring in the state.<sup>36</sup> In 2015, the number of opioid-related overdose deaths in Ohio reached a staggering 2,590.<sup>37</sup>

Table 1. Unintentional Drug Overdose Deaths of Ohio Residents Involving Specific Drug(s), as Mentioned on Death Certificate, by Year, 2003-2015<sup>1-3</sup>

Drug Category	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	% of 2015 deaths
All opioids*	296	429	489	551	631	733	783	980	1,163	1,272	1,539	2,020	2,590	84.9%
Heroin	87	124	131	117	146	233	283	338	431	680	983	1,196	1,424	46.7%
Fentanyl					4	6	7	5	0	75	84	503	1,155	37.9%
Prescription opioids**	221	319	388	462	504	538	543	692	795	628	644	672	667	21.9 %
Benzodiazepines	38	69	90	121	133	154	211	300	376	311	328	420	504	16.5%
Cocaine	140	221	223	317	287	252	220	213	309	326	405	517	685	22.5%
Alcohol	40	38	58	89	135	181	173	195	226	282	304	383	380	12.5%
Methadone	55	116	144	161	176	168	169	155	156	123	112	103	108	3.5%
Hallucinogens	7	8	8	10	13	14	9	26	31	31	43	49	61	2.0%
Barbiturates	5	3	5	3	7	3	5	13	11	6	10	6	19	0.6%
Other/unspecified drugs only***	154	256	289	378	453	475	396	343	376	389	319	274	194	6%
Multiple Drug Involvement								888 <sup>4</sup>	980 <sup>5</sup>	1,016 <sup>6</sup>	1,014 <sup>7</sup>	1,321 <sup>8</sup>	1,747 <sup>9</sup>	
Total unintentional poisoning deaths	658	904	1,020	1,261	1,351	1,473	1,423	1,544	1,772	1,914	2,110	2,531	3,050	
Age-adjusted annual death rate per 100,000	5.8	7.9	8.9	11.0	11.7	12.8	12.5	13.7	15.6	17.1	18.8	22.8	27.7	

Source: Ohio Department of Health, Bureau of Vital Statistics; Analysis by ODH Injury Prevention Program.

154. From 2004-2016, Clinton County experienced the ninth highest overdose rate per 100,000 population in the entire state of Ohio.

155. From 2011-2016, Clinton County had 80 overdose deaths. From 2005-2010 (the immediately prior 6-year period), Clinton County only had 42 overdose deaths. And none of these statistics take into account that not all overdoses result in death.

<sup>36</sup> The Henry J. Kaiser Family Foundation Overdose Deaths, 2014 and 2015.

<sup>37</sup> Courtney Astolfi, *Report: Ohio ground-zero for opioid overdose deaths*, Cleveland.com (Nov. 30, 2016), available at: [http://www.cleveland.com/metro/index.ssf/2016/11/report\\_ohio\\_ground-zero\\_for\\_op.html](http://www.cleveland.com/metro/index.ssf/2016/11/report_ohio_ground-zero_for_op.html).

156. Opioid-related death tolls are rising at such a rapid pace that cities and counties are unable to keep up logistically. As an example, in 2016, one coroner's office had to use refrigerated trucks to store bodies for an entire week because the city was unable to process cases as fast as individuals were fatally overdosing. In 2017, the same coroner's office was forced to request, for the first time ever, that a local funeral parlor provide temporary storage for bodies that it simply lacked the capacity to hold.<sup>38</sup>

157. Manufacturer Defendants' deceptive marketing scheme has also had a significant detrimental impact on children in Ohio in a number of ways. First, the overprescribing of opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household. An Ohio Department of Health survey of high school students revealed that, from 2011 to 2013, 12.8 percent of students illegally used prescription painkillers like OxyContin.<sup>39</sup>

158. Additionally, Ohio's child protection agencies experienced a 9% increase in the number of children – nearly 1,100 – in foster care between December 2011 and December 2015, driven by parental drug addiction.<sup>40</sup> Seventy percent of infants placed the foster care system in Ohio are children of parents with opiate addictions.<sup>41</sup> Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant

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<sup>38</sup> Kimiko de Freytas-Tamura, *Amid Opioid Overdoses, Ohio Coroner's Office Runs Out of Room for Bodies*, N.Y. Times (Feb. 2, 2017).

<sup>39</sup> Ohio Department of Health, 2013 Ohio Youth Risk Behavior Survey: Illegal Drug Use and Prescription Drug Abuse.

<sup>40</sup> Public Children Services Association of Ohio, *Ohio's Opiate Epidemic and Child Protection* (2016).

<sup>41</sup> Ohio Child Welfare Opiate Engagement Project (Sept. 2014).

trauma, which makes these cases more expensive to deal with.<sup>42</sup> The crisis has affected Clinton County children and its department of job and family services in the same way. Clinton County spends an estimated \$26 million on children's services, and the opioid crisis has created demands for increased funds such as an additional \$500,000 built in the budget for addiction services in recent years.

159. The overprescribing of opioids for chronic pain caused by Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Ohio who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw. In 2013, the average inpatient stay and bill for NAS infants was four times longer and four times higher than for other Ohio infants.<sup>43</sup> Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014 with health care costs totaling \$105 million.<sup>44</sup> In 2014, 1,875 babies with NAS were admitted to inpatient settings in Ohio – an average of more than 5 per day. In April 2016, it was reported by the Ohio Perinatal Quality Collaborative that 4,000 babies had been treated for NAS at Ohio hospitals during the preceding 18 month period.<sup>45</sup>

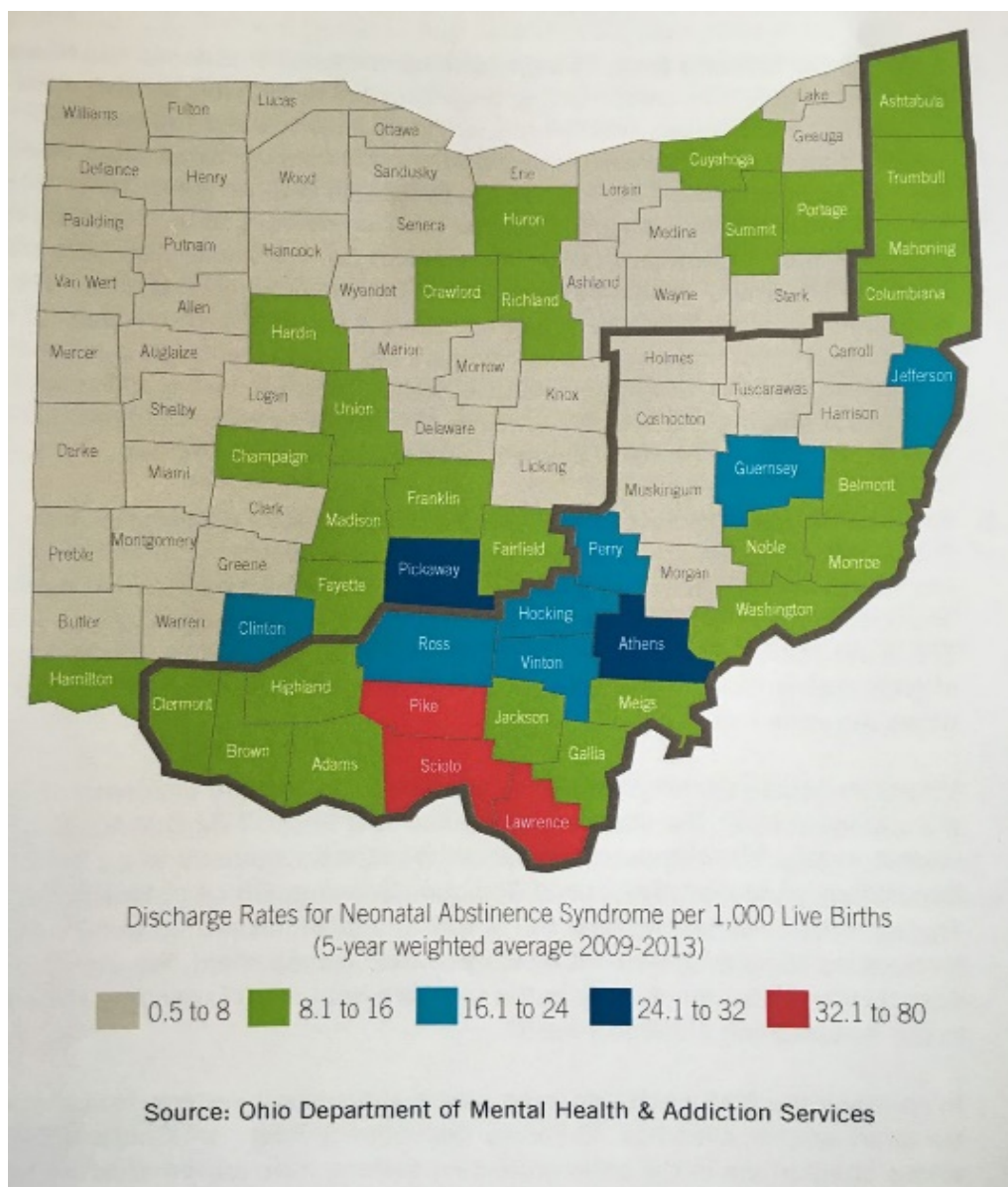
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<sup>42</sup> Trista Thurston, *Drug addiction drives spike in Ohio foster care*, Newark Advocate (Mar. 23, 2017).

<sup>43</sup> Ohio Department of Health (2013). Neonatal abstinence syndrome (NAS) in Ohio, 2004- 2013, preliminary report. Retrieved from <http://www.healthy.ohio.gov/~media/HealthyOhio/ASSETS/Files/injury%20prevention/NAS%20Summary%20Report%200317b.pdf>.

<sup>44</sup> Ohio Maternal Opiate Medical Supports (M.O.M.S.) Project, 2016 Infant Mortality Summit.

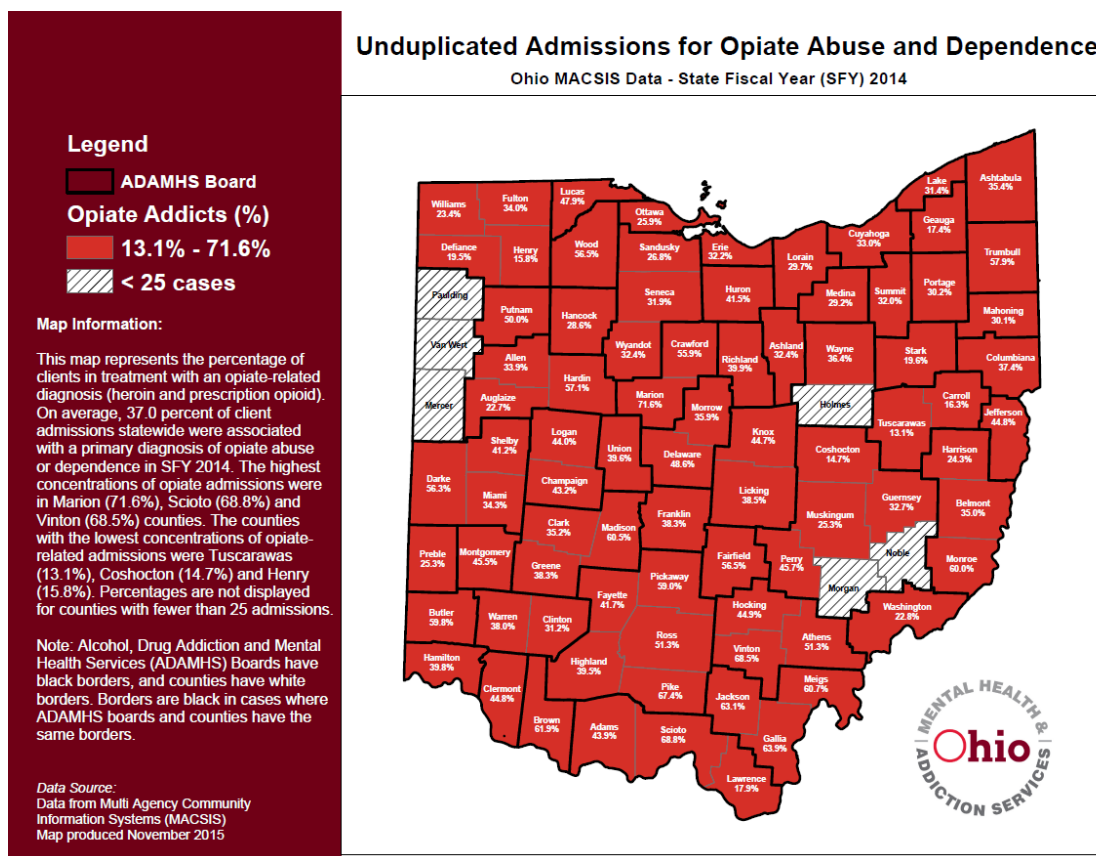
<sup>45</sup> Christopher Evans, Cleveland.com, *Addiction city: Ohio's opiate addicts would make the fifth largest city in the state*, <http://www.cleveland.com/metro/index.ssf/2016/04/--the-heroin-crisis-in-ohio.html> (last accessed May 12, 2017).



160. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. In 2014, 37% of admissions for drug abuse were associated with a primary diagnosis of opiate abuse or dependence.<sup>46</sup> In 2016, there were 200,000 opioid addicts in the state – roughly equivalent to the entire population of the city of Akron.<sup>47</sup>

<sup>46</sup> Unduplicated Admission for Opiate Abuse and Dependence, Ohio MACSIS Data State Fiscal Year 2014.

<sup>47</sup> Ohio Automated RX Reporting System, 2016 Annual Report.



161. Since 2014, the state has repeatedly increased spending on Medication Assisted Treatments (“MATs”) to address opioid addiction. Expenditures on MATs have more than doubled from \$40 million in 2014 to over \$110 million in 2016. This expense is in addition to treatment and counseling services which cost the state another \$462 million between 2014 and 2016.<sup>48</sup>

162. The number of emergency medical services (“EMS”) runs for suspected opioid-related overdose has also increased. Between 2003 and 2012, Naloxone, a drug used to reverse opiate-induced overdoses, was administered approximately 74,000 times by Ohio EMS personnel *alone*. The number of EMS Naloxone administrations per year grew from 4,010 in

<sup>48</sup> Rachel Dissell, *Ohio’s spending on opioid addiction treatment drugs Vivitrol and Suboxone spikes, spurs debate on what treatments work*, Cleveland.com (Apr. 30, 2017).

2003 to 10,589 in 2012 – a 164% increase. This means that, on average, there were 11 emergency administrations of Naloxone per day in 2003 and 29 per day in 2012.<sup>49</sup> In 2015, that figure went up even more, with Ohio EMS personnel administering a total of 19,782 doses.<sup>50</sup>

163. Manufacturer Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities throughout Ohio. Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.<sup>51</sup>

164. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as

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<sup>49</sup> Massatti, R. (2013, November), *Naloxone (Narcan) Administration in Ohio, 2003-2012*. Columbus, OH: Ohio Department of Mental Health and Addiction Services.

<sup>50</sup> Ohio Department of Health News Release, *Illicit Fentanyl Continues to Fuel Increase in Drug Overdose Deaths in Ohio* (Aug. 25, 2016).

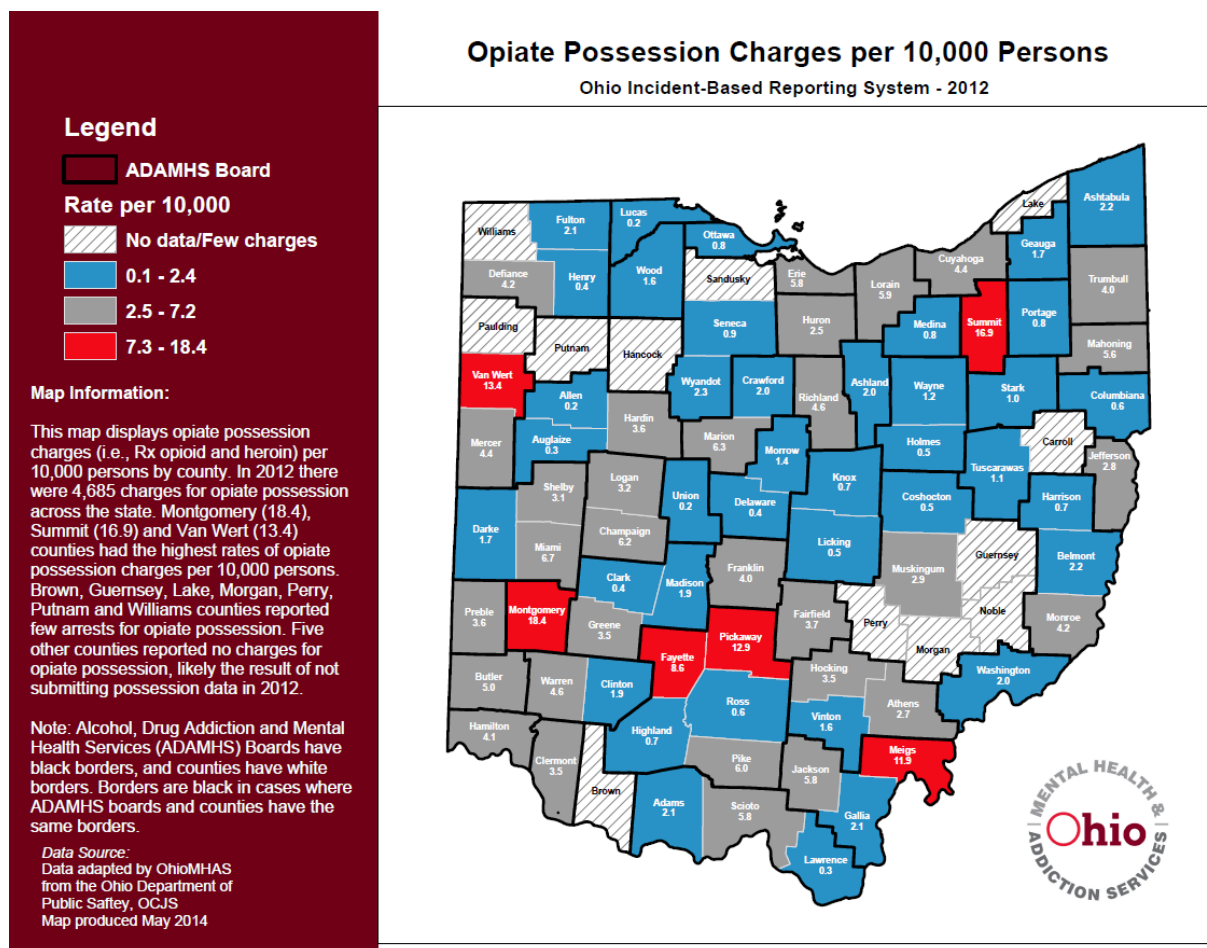
<sup>51</sup> Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), available at <http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers>.

OxyContin and Percocet, in order to protect themselves from robbery. This ongoing diversion of prescription narcotics creates a lucrative marketplace. For example, the Ohio Substance Abuse Monitoring Network recently released their report on “Drug Abuse Trends in the Cleveland Region.” The report is associated with the Ohio Department of Mental Health and Addiction Services, and was “based upon qualitative data collected via focus groups interviews” of “active and recovering drug users recruited from alcohol and other drug treatment programs in Cuyahoga, Geauga and Lake Counties.” That report, which observed that “prescription opioids remain highly available in the region,” found the following street prices for prescription opioids:

Prescription Opioids	Current Street Prices for Prescription Opioids	
	Dilaudid®	\$20 for 8 mg
	fentanyl	\$150 per patch (unspecified dose)
	methadone	\$40 for 90 pills (unspecified dose) \$60 for 30-day liquid supply (unspecified dose)
	Opana®	\$2 per mg
	OxyContin®	\$100 for 80 mg
	Percocet®	\$7 for 5 mg \$10 for 7.5 mg \$14 for 10 mg
	Vicodin®	\$2-4 for 5 mg \$7-8 for 10 mg

Thus, for example, a bottle of 100 80-mg tablets of OxyContin would have a street value of anywhere between \$1,600 and \$4,000.

165. The number of criminal possession charges for opioid drugs has also increased. In 2014, there were 5,562 charges for opiate possession across the state. That number rose from 5,115 in 2013 and 4,685 in 2012.<sup>52</sup>



166. The rise in opioid addiction caused by Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids. A study by the Ohio Substance Abuse Monitoring Network found that, "young new heroin abusers seeking treatment

<sup>52</sup>

Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

reported OxyContin abuse prior to becoming addicted to heroin.”<sup>53</sup> In 2014 and 2015, Ohio recorded the largest number of heroin-related fatal overdoses of any state – with 1 in every 9 deaths in the United States occurring in Ohio.<sup>54</sup> Heroin-related deaths accounted for 1,424 unintentional drug overdose deaths in 2015, an increase from 1,196 in 2014. In 2015, heroin was involved in 46.7% of all overdose deaths in the state of Ohio.<sup>55</sup>

167. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement.<sup>56</sup> In addition, the resulting costs of unintentional drug overdose are shocking; unintentional fatal drug overdoses cost Ohioans \$2 billion in 2012 while non-fatal hospital admitted drug poisonings cost an additional \$39.1 million. In 2012, the total cost to the state averaged \$5.4 million *per day* in medical and work loss expenses.<sup>57</sup>

168. Manufacturer Defendants knew and should have known about the harm that their deceptive marketing has caused. Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended

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<sup>53</sup> Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

<sup>54</sup> The Henry J. Kaiser Family Foundation Overdose Deaths, 2014 and 2015.

<sup>55</sup> 2015 Ohio Drug Overdose Data: General Findings.

<sup>56</sup> Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

<sup>57</sup> Ohio Department of Health, Prevalence and Trends in Unintentional Drug Overdose.

CMEs, knew which doctors were receiving their messages and how they were responding. Manufacturer Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

169. Manufacturer Defendants’ actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Manufacturer Defendants’ misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

170. Nor is Manufacturer Defendants’ causal role broken by the involvement of doctors. Manufacturer Defendants’ marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients’ suffering and of practicing medicine more compassionately.

**F. Manufacturer Defendants’ Fraudulent Marketing Has Led To Record Profits.**

171. While the opioid crisis has taken an enormous toll on the state of Ohio and specifically Clinton County, which has sustained substantial economic injury, Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue,

and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

**V. FACTUAL ALLEGATIONS REGARDING DISTRIBUTOR DEFENDANTS**

172. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

173. The supply chain for prescription drugs begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants AmerisourceBergen, Cardinal, and McKesson, which together account for 85-90% of all revenues from drug distribution in the United States, estimated to be at \$378.4 billion in 2015. Distributor Defendants then supply controlled substances to pharmacies, hospitals, and other healthcare providers, which then, in turn, dispense the drugs to individuals.

174. Each participant in the supply chain is responsible for controlling the availability of prescription drugs. Diversion occurs whenever the supply chain of prescription drugs is broken, and the drugs are transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use.

175. Prescription drug diversion occurs in the United States at an alarming rate. For example, in recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

**A. Distributor Defendants' Duties are well established.**

176. The federal and state Controlled Substances Acts ("CSAs") function as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the ultimate user (*i.e.*, "the maker to the taker"). Every person or entity who manufactures, distributes, or dispenses controlled substances must obtain a "registration" with

the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA; otherwise controlled substances move from the licit to the illicit marketplace, and there is great potential for foreseeable harm to the general public.

177. Ohio regulations similarly require those wholesalers “distributing dangerous drugs” to be licensed and registered. *See, e.g.*, Ohio Admin. Code § 4729-9-16.

178. The applicable Ohio regulations regarding diversion provide: “All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion.” Ohio Admin. Code § 4729-9-05(A). The aforementioned “requirements” are imbedded in § 4729-9-11 to “deter and detect diversion” and to further elucidate the responsibility to “monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.” Ohio Admin. Code § 4729-9-11(C).

179. As part of the requirement to have an effective anti-diversion program, Ohio regulations specifically mandate that a system “shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse” and that “[t]he wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.” Ohio Admin. Code § 4729-9-16(H)(1)(e).

180. Ohio regulations also require that “[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.” Ohio Admin. Code § 4729-9-16(L).

181. Similar to the Ohio requirements, Distributor Defendants are governed by the statutory requirements of the federal Controlled Substances Act (“CSA”), 21 U.S.C. § 801, *et seq.*, and its corresponding regulations. These requirements create a legal framework for the distribution and dispensing of controlled substances and were enacted to protect society from the harms of drug diversion. Congress passed the CSA partly out of a concern about “the widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 4572.

182. Under Part 1301 of Title 21 of the Code of Federal Regulations, entitled REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES, the following applicable regulation is set forth: “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). To reiterate, this concomitant federal duty is further incorporated into Ohio state law by virtue of the aforementioned Ohio Admin. Code § 4729-9-16(L).

183. In order to be properly registered, the Distributor Defendants must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. *See* 21 U.S.C. § 823(b).

184. Under both Ohio and federal law, the Distributor Defendants are required to maintain effective controls and procedures to deter and detect diversion of dangerous drugs. As part of this requirement of having an effective anti-diversion program, the Distributor Defendants, at a minimum, must do all of the following: (a) conduct due diligence and know their customers and their customer's customers such that unscrupulous pharmacy customers can be identified, terminated as customers and reported to law enforcement; (b) design and operate a system that effectively identifies and detects all suspicious orders; (c) monitor, detect, and otherwise track all suspicious orders; (d) promptly report all suspicious orders to all applicable law enforcement, including both the DEA and the Ohio Board of Pharmacy; (e) refuse to ship suspicious orders; (f) terminate their business relationship with pharmacy customers if there are indications of diversion; and (g) generally prevent diversion of prescription drugs into illicit markets.

185. Distributor Defendants have a common law duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct – and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another – is under a duty to exercise reasonable care to prevent the threatened harm.

186. Tellingly, the Distributor Defendants recognized their statutory and common-law duties when they assisted in the creation of the 2008 version of the HDMA Guidelines, which provides: “HDMA’s members have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”

187. As background, the Distributor Defendants all have had or currently have executive members on the Board of Directors of the Healthcare Distribution Management Association (“HDMA”), now the Healthcare Distribution Alliance (“HDA”), an industry trade association for wholesalers and distributors. Cardinal’s former CEO was the past Chairman of the Board; AmerisourceBergen’s president has been and currently sits on the Board; and McKesson’s president has been and currently sits on the Board.

188. The 2008 HDMA guidelines were entitled, “Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,” and provide: “At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.” The 2008 HDMA Industry Guidelines contain the following elements:

- I. Know Your Customer Due Diligence
- II. Monitoring for Suspicious Orders
- III. Suspend/Stop an Order of Interest Shipment
- IV. Investigation of Orders of Interest
- V. File Suspicious Order Reports with DEA
- VI. Employees, Training and Standard Operating Procedure (SOP)
- VII. Additional Recommendations

189. The guidelines’ first element of “Know Your Customer” provides that distributors must gather substantial information on each of its customers, including, *inter alia*, their business background, customer base, average number of prescriptions filled each day, average number of controlled substances item prescriptions filled each day, percentage of controlled substance purchases compared to overall purchases, among additional information. According to these industry guidelines, this information must be reviewed carefully by the distributor, and the distributor must conduct a thorough, independent investigation of the customer.

190. The HDMA Guidelines further underscore the Distributor Defendants' recognition of the duties required of them in operating an effective program to combat diversion.

191. In addition to activities through their trade organization, the managements of the Distributor Defendants have recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made public statements assuring communities that they are supposedly undertaking a duty to curb the prescription drug epidemic.

192. In an August 12, 2016 interview with the *Philadelphia Inquirer*, AmerisourceBergen's CEO acknowledged: "The U.S. Drug Enforcement Agency: They have to control prescription drug abuse, and it's a tremendous problem in this country. . . . We can say, 'This pharmacy in Ohio is ordering too much of this product.' That's called suspicious-order monitoring."

193. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

194. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

195. At the very least, these assurances about constantly eliminating criminal activity and curbing the prescription drug epidemic create a duty for Distributor Defendants to reasonably follow through. Besides, such measures are precisely what the state and federal laws require.

196. Thus, in addition to the obligations imposed by law, through their own words and

actions, Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the prescription drug epidemic.

197. Distributor Defendants' violations of these federal and state requirements show that they failed to meet the relevant legal standard of conduct and the level of responsibility that society expects from them.

**B. Distributor Defendants Knew They Owed Duties under Federal and State Law and that their Continued Breach of those Duties would Further Facilitate Widespread Diversion of Prescription Drugs and Fuel the Prescription Drug Epidemic.**

198. The problem of prescription drug diversion in the supply chain has been widely publicized. Numerous publications, studies, federal agencies, and professional organizations have highlighted the epidemic rate of opioid abuse and overdose rates in communities in Ohio, as well as throughout the United States.

199. To combat the problem of opioid diversion, the DEA has provided guidance to Distributor Defendants in numerous venues, publications, documents, and final agency actions on some of the requirements of an effective anti-diversion program.

200. Since 2006, the DEA conducted one-on-one briefings with Distributor Defendants regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided Distributor Defendants with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled versus non-controlled purchases. Distributor Defendants were also given case studies, legal findings against other registrants, and profiles of their customers in the Automation of Reports and Consolidated Orders System ("ARCOS") whose previous purchases may have reflected suspicious ordering patterns. The DEA pointed

out some of the “red flags” that distributors should look for in order to identify potential diversion. This initiative was created to help distributors further understand their duties with respect to diversion control.

201. Since 2007, the DEA has hosted no fewer than five conferences to provide Distributor Defendants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All Distributor Defendants attended at least one of these conferences.

202. On September 27, 2006, and again on December 27, 2007, the DEA Office of Diversion Control sent letters to Distributor Defendants, as well as all other registered distributors, providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant-distributor to conduct due diligence on controlled substance pharmacy customers as part of their required program to maintain effective controls against diversion.

203. The September 27, 2006 letter reminded registrants that they are required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. In noting that even just one distributor facilitating diversion can “cause enormous harm,” the letter provided the following regarding Distributor Defendants’ role in the closed distribution system:

one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

204. The September 27, 2006 letter explained that as part of the legal obligation to maintain effective controls against diversion, Distributor Defendants are required to exercise due care in confirming the legitimacy of all orders prior to filling. That is, the letter expressly states

that Distributor Defendants, in addition to reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” It also described circumstances that could be indicative of diversion including the ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; the disproportionate ratio of ordering controlled substances to non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and the ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

205. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants, including Distributor Defendants, reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that filing a suspicious order report and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review the recent DEA action called *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), which addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

206. These DEA letters made it abundantly clear to Distributor Defendants that the prescription drug epidemic was ravaging communities throughout the United States and that

Distributor Defendants must act as a gatekeeper by providing an effective anti-diversion program. They have failed to serve as such a gatekeeper or safeguard.

207. Moreover, Distributor Defendants were on notice that their own industry group, the aforementioned HDMA, published Industry Compliance Guidelines titled “Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,” in 2008 that stressed the critical role of the distributors in combating diversion and over-supply of controlled substances.

**C. Distributor Defendants breached the duties they owed.**

208. Despite all of this, Distributors Defendants negligently, recklessly, and knowingly allowed diversion to proliferate and over-supplied its pharmacy customers. Their misconduct has resulted in numerous civil fines and other penalties recovered by state and federal agencies, including actions by the DEA related to violations of the Controlled Substances Act and by the State of West Virginia for, *inter alia*, alleged violations of the West Virginia Controlled Substances Act.

**1. Distributor Defendants paid substantial fines and settlements for their failures to maintain effective controls against diversion.**

209. AmerisourceBergen has had its distribution center’s license suspended, acknowledged being under federal scrutiny, and paid a substantial amount to the State of West Virginia to settle allegations relating to failures in its anti-diversion program.

210. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida, distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

211. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels. As reported in the media, the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes." In an SEC filing, AmerisourceBergen acknowledged that "since fiscal 2013" it had "received subpoenas from the United States Attorney's Offices in the District of Kansas and the United States Attorney's Office in the Northern District of Ohio in connection with grand jury proceedings requesting documents concerning ABDC's program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

212. In late 2016, AmerisourceBergen reached a settlement with the state of West Virginia to pay \$16 million to resolve claims that it, *inter alia*, violated the West Virginia Controlled Substances Act and flooded that State with prescription drugs.

213. Among other things, Cardinal has paid a \$34 million fine to the DEA in 2008 and a \$20 million settlement in 2016 to the state of West Virginia and an additional \$44 million to the DEA in 2017 for allegations similar to those described herein.

214. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone.

215. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida, Distribution Center for failure to maintain effective controls against diversion of hydrocodone.

216. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey, Distribution Center for failure to maintain effective controls against diversion of hydrocodone.

217. On January 30, 2008, the DEA issued an issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas, Distribution Center for failure to maintain effective controls against diversion of hydrocodone.

218. On September 30, 2008, Cardinal Health entered into an *Administrative Memorandum of Agreement* (“MOA”) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The 2008 MOA also alleged that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in Valencia, California, and Denver, Colorado. In 2008, Cardinal paid a \$34 million penalty to settle allegations about prescription drug diversion taking place at these seven warehouses around the United States.

219. A few years later, on February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal’s Lakeland, Florida, Distribution Center for failure to maintain effective controls against diversion of oxycodone. In that case, the DEA alleged Cardinal sent a “staggeringly high” volume of pills to various dispensers that posed “an imminent danger to public health or safety.” The DEA further alleged Cardinal otherwise failed to report suspicious orders.

220. Since resuming operations in October 2008, Lakeland had not alerted DEA about a single suspicious order for three of its top four customers, even though two of them have surrendered their DEA registrations due to committing the very sort of diversion DEA expected Cardinal and all distributors to police. Indeed, the DEA explained the orders that Cardinal

flagged as suspicious were overwhelmingly released with little or no explanation as to why. Even those few orders that Cardinal refused to fill as suspect it failed to report to DEA, as Cardinal was required to do. During that time, Cardinal never conducted an in-store audit of the pharmacies, despite DEA having told Cardinal that it could not fulfill its due diligence obligations simply by relying on the pharmacies' controls.

221. When Cardinal's investigations did raise red flags, they were frequently ignored. In October 2010, for example, a Cardinal investigator suspected that a pharmacy was illegitimately dispensing oxycodone, and recommended that Cardinal call the DEA. Not only was that call never made, Lakeland [Cardinal's location] increased oxycodone volume to this pharmacy in the months after the visit, notwithstanding the investigator's warning that this particular pharmacy posed a "high risk of diversion." Indeed, Cardinal's opioid shipments to the pharmacy increased to almost 2 million doses of oxycodone in one year to a town with a population of 53,000, while other comparable pharmacies were obviously receiving much less. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In the agreement it reached with the DEA in May 2012, Cardinal admitted that it had inadequate control over some of its prescription drugs. On December 23, 2016, Cardinal Health agreed to pay an additional *\$44 million* fine to the DEA to resolve the civil penalty portion of the Administrative action taken against its Lakeland, Florida, Distribution Center and for its failures in reporting additional suspicious orders of pharmacies in Maryland and New York.

222. Just prior to the announcement of that payment, in December of 2016, Cardinal reached a settlement with the state of West Virginia for *\$20 million* to settle allegations that it

did not have an effective anti-diversion program and over-supplied the State with prescription drugs.

223. McKesson similarly paid fines of *\$13.25 million* in 2008 and *\$150 million* in 2017 for its failures associated with its anti-diversion program.

224. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 Agreement”) with the DEA that provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.” McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a *\$13.25 million* civil fine. In the 2008 Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious order to DEA,” but had failed to do so.

225. After the 2008 settlement, McKesson continued its wrongful conduct. It was revealed that McKesson’s system for detecting “suspicious orders” from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of doses of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

226. Again in 2015, McKesson found itself in the middle of allegations concerning its “suspicious order reporting practices for controlled substances.” In early 2017, McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an *Administrative Memorandum of Agreement* (“2017 Agreement”) entered into between McKesson

and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009, through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies” that should have been detected by McKesson. Further, the 2017 Agreement specifically finds that McKesson distributed controlled substances to pharmacies, even though those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a). McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers,” including the McKesson Distribution Center located in Washington Courthouse, Ohio. Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Ohio facility (among other facilities) would be partially suspended. The 2017 Agreement indicates that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.” As a result of these violations, McKesson paid the United States a fine of *\$150 million*.

**2. Distributor Defendants’ Anti-Diversion Programs were fundamentally flawed.**

227. Because Distributor Defendants handle such large volumes of controlled substances and are the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent upon Distributor

Defendants to maintain effective controls to prevent diversion of controlled substances. Should a Distributor Defendants deviate from these checks and balances, the closed system collapses, especially given their overwhelming market share in distribution of opioids.

228. The sheer volume of prescription drugs, including opioids, distributed to pharmacies in the County is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in legitimate distribution of controlled substances can reasonably claim ignorance of them.

229. Distributor Defendants failed to report suspicious orders originating from the County to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

230. Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency in the County.

231. Distributor Defendants breached their duty to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription drugs originating from the County.

232. Distributor Defendants breached their duty to maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, and industrial channels in the following ways:

- To the extent Distributor Defendants developed anti-diversion programs after the explosion of the prescription drug epidemic, those programs were perfunctory and ineffective.
- Distributor Defendants set threshold or benchmark levels (as indicated in the HDMA Guidelines) for certain kinds of controlled substances that it must have known were too high.
- When those threshold or benchmark levels were exceeded, the Distributor Defendants, by and large, ignored or dismissed this information.

- Distributor Defendants failed to adequately monitor their pharmacy customers' purchase of the "holy trinity" of prescription drugs (*i.e.*, opioid, benzodiazepine, and carisoprodol), which is a telltale sign of abuse of such controlled substances for illegitimate purposes.
- Distributor Defendants failed to adequately monitor their pharmacy customers' purchase of maximum strength opioids, which is another telltale sign of abuse of such controlled substances for illegitimate purposes.
- Distributor Defendants did not act on purchases involving high percentages of controlled substances vis-à-vis purchases of non-controlled substances.
- Distributor Defendants' site visits to pharmacies was not conducted with any kind of scrutiny but fell in line with the perfunctory nature of the so-called "anti-diversion" program.
- Distributor Defendants ignored long lines, out-of-state purchasers, and large numbers of cash transactions during its "investigations" of its customer pharmacies. These are all, of course, indicators of diversion and dangerous controlled substances otherwise being disseminated for illegitimate purposes.
- Distributor Defendants' sales personnel benefited from the sale of these prescription drugs and had an undue influence on the anti-diversion division of their respective companies, thus improperly creating incentives that contributed to and exacerbated drug diversion and the resulting epidemic of prescription drug abuse.
- Distributor Defendants did not punish, censure, or cease doing business with their unscrupulous pharmacy customers in any meaningful way because the orders of opioids and other commonly-abused prescription drugs continued to flow to those pharmacies.
- Distributor Defendants did not adequately consider the population base of the area where the shipments of controlled substances were being sent.
- Distributor Defendants improperly considered the prior ordering history of high-selling pharmacy customers as a baseline for their subsequent purchases as the DEA letters make reference to this phenomenon.
- Distributor Defendants' due diligence investigations of its pharmacy customers were inadequate, insufficient, and perfunctory.

233. Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the

authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

234. Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.

235. The federal and state laws at issue here are public safety laws.

236. Distributor Defendants' violations of public safety statutes constitute *prima facie* evidence of negligence under Ohio law.

237. The unlawful conduct by Distributor Defendants is purposeful and intentional. Distributor Defendants refuse to abide by the duties imposed by federal and state law that are required to legally acquire and maintain a license to distribute prescription drugs, including opioids.

238. Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have consciously disregarded the rights and safety of other persons. These actions have caused substantial harm to the County.

239. Distributor Defendants' made repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities. This demonstrates wanton, willful, or reckless conduct, or criminal indifference to civil obligations affecting the rights of others, and justifies an award of punitive damages.

240. Distributor Defendants had the ability and duty to prevent prescription drug diversion, which presented a known or foreseeable danger of serious injury to the County. But they failed to do so.

241. Distributor Defendants have supplied quantities of prescription drugs in and around the County with the actual or constructive knowledge that many of the prescription drugs were ultimately being consumed by County citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Distributor Defendants negligently, recklessly, and intentionally failed to do so.

242. Each Distributor Defendant knew or should have known that the amount of opioids and other prescription drugs that it allowed to flow into the County was far in excess of what could be consumed for medically necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only drug distributor servicing those communities).

243. Distributor Defendants negligently, recklessly, and intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of prescription drug diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the County; providing information to pharmacies and retailers about prescription drug diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies.<sup>58</sup>

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<sup>58</sup> Rather than abide by their non-delegable duties under public safety laws, Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress for a “sharp drop in enforcement actions” and the

**D. Distributor Defendants' misconduct has caused and continues to cause injury to the County.**

244. As aforesaid, each Distributor Defendant repeatedly and intentionally breached their duties under state and federal law.

245. These breaches are a direct and proximate cause of the widespread diversion of prescription drugs for non-medical purposes in the County and the consequent scourge of the prescription drug epidemic sweeping the County for which the County must pay and endure. These harms were reasonably foreseeable to Distributor Defendants.

246. It was reasonably foreseeable to Distributor Defendants that their conduct in flooding the market in and around the County with highly-addictive opioids and other prescription drugs would allow opioids and other prescription drugs to be diverted and fall into the hands of children, addicts, criminals, and other unintended users for nonmedical purposes.

247. Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would cause the prescription drug epidemic of the County, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, and illegal activity generally.

248. Availability and accessibility leads to abuse. Demonstrating this point is the nationwide spike in the prevalence of opioids and overdose deaths. Between 1999 and 2015, both quadrupled and not coincidentally. Moreover, a comparison of the opioid epidemic sweeping this country as compared to those countries where the prevalence of opioids is much lower leads to the same conclusion.

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passage of the "Ensuring Patient Access and Effective Drug Enforcement Act," which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.

249. It is reasonably foreseeable to Distributor Defendants that, when unintended users gain access to opioids and other prescription drugs, tragic preventable injuries will result, including addiction, overdoses, and death.

250. It is reasonably foreseeable to Distributor Defendants that the opioid epidemic would cause addicts and other users to switch to the closely related pharmacological substance of heroin.

251. It is reasonably foreseeable to Distributor Defendants that state and local governments would bear the costs of dealing with the prescription drug and related heroin epidemics fueled by Distributor Defendants' failure to comply with their legal duties.

252. Distributor Defendants knew or should have known that a substantial amount of opioids and other prescription drugs dispensed in and around the County were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids and other prescription drugs will cause harm to individual pharmacy customers, third-parties, and the County.

253. Distributor Defendants were aware of widespread prescription drug abuse in and around the County, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in the County and surrounding areas-- and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

254. The use of opioids and other prescription drugs by County citizens who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of Distributor Defendants. If Distributor Defendants

adhered to effective controls to guard against diversion, the County and its citizens would have avoided significant injury.

255. Distributor Defendants made substantial profits over the years based on the diversion of opioids and other prescription drugs into the County. Their participation and cooperation in a common enterprise has foreseeably caused injuries the citizens of the County and financial damages to the County. Distributor Defendants knew full well that the County would be unjustly forced to bear the costs of these injuries and damages.

256. Distributor Defendants' intentional distribution of excessive amounts of opioids and other prescription drugs to relatively small communities primarily serving County citizens showed an intentional or reckless disregard for the safety of the County and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the County.

257. Distributor Defendants created conditions in which vast amounts of controlled substances flowed freely from manufacturers to end user abusers.

258. The County and other governmental entities paid for and otherwise endured the considerable damage caused by Distributor Defendants. Defendants have thus foreseeably caused past damages to the County including the costs of providing: (1) medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from controlled substances-related addiction or disease, including overdoses and deaths; (2) counseling and rehabilitation services; (3) treatment of infants born with controlled substances-related medical conditions; (4) welfare for children whose parents suffer from controlled substances-related disability or incapacitation, including, but not limited to, additional costs incurred by the foster care network, by way of one example; and (5) law enforcement and public safety relating to the prescription drug epidemic within the County. The County has also

suffered substantial damages relating to the lost productivity of County citizens and businesses. The County will continue to suffer future damages in attempting to abate the public nuisance caused by Defendants, as explained more fully below. Additional damages suffered by the County are described throughout the Complaint.

259. The County expressly indicates that it does not seek any relief in this action for the federal share of funding for the State Medicaid Program. Claims of damages for any federal monies expended are hereby expressly disavowed.

## **VI. CLAIMS FOR RELIEF**

260. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

### **DISCOVERY RULE TOLLING**

261. Clinton County could not have discovered through the exercise of reasonable diligence that Defendants' conduct alleged in this Complaint would have the drastic, deleterious effects on Clinton County and across Ohio within the time period for all applicable statutes of limitations.

262. Among other things, Clinton County could not have known and appreciated the actions taken by Manufacturer Defendants to convince physicians that opioids were healthy alternatives for chronic pain, including, but not limited to, the use of Key Opinion Leaders, non-profit entities encouraging their prescribing for chronic pain, and other means taken to legitimize the use of opioids for chronic pain against hundreds of years of medical science.

263. Clinton County similarly could not have known about the inexorable amounts of opioid pills that distributors shipped into the County, especially given the lengths at which

Distributor Defendants and the Drug Enforcement Agency have gone to keep its database and related information out of the public view.

### **FRAUDULENT CONCEALMENT TOLLING**

264. Throughout the time period relevant to this action, Defendants concealed from and/or failed to disclose to Clinton County and all counties across Ohio the adverse health effects of opioids and the extent of their addictiveness. Indeed, Defendants could have – *and should have* – disclosed all facts alleged in this Complaint to Clinton County and its citizens at least by the early 2000s , so that Clinton County officials and citizens could have taken measures in an effort to abate the negative effects of Defendants’ actions. Instead, Defendants kept Clinton County and all counties across Ohio ignorant of information essential to the pursuit of these claims, and, as a result, Clinton County could not have discovered the Defendants’ claims, even upon reasonable exercise of diligence.

265. Specifically, and as described in greater detail throughout the Complaint, Defendants have been aware at least since their actions began in the early 2000s that opioids were dangerous substances for which special precautions must be taken, such as providing physicians with accurate and fulsome information and carefully watching the volumes of opioids that enter specific geographic regions.

266. Despite knowledge of their actions and inactions, Defendants failed to disclose to and actively concealed their improper actions from Clinton County and all counties across Ohio, even though it could have disclosed their actions at any point in time through individual correspondence with opioid pill recipients, physicians, media release, or any other means.

267. Defendants have also repeatedly and expressly denied that their marketing and distribution activities, as outlined in the Complaint, affected people in any way.

268. By failing to disclose the inaccuracies with representations and lack of checks and balances on distribution, Defendants fueled the current health crisis for years and years without ever fully disclosed the facts to Clinton County or any county across Ohio. Defendants remained silent and continued to mislead Clinton County officials and the citizens of Clinton County.

269. Clinton County and all counties across Ohio justifiably relied on Defendants to disclose their actions and/or inactions, as such activities and misconceptions in the marketplace were hidden and not discoverable through reasonable efforts by Clinton County.

270. Thus, the running of all applicable statutes of limitation has been suspended with respect to any claims that Clinton County has sustained by virtue of the fraudulent concealment doctrine.

### **ESTOPPEL**

271. Knowing the grave harm that Defendants have caused Clinton County and its citizens, Defendants were under a continuous duty to disclose the true character, quality, and nature of the opioid pills that they manufactured and distributed.

272. Based upon the foregoing, Defendants are estopped from relying on any statutes of limitation in defense of this action.

### **COUNT ONE**

#### **PUBLIC NUISANCE OHIO PRODUCT LIABILITY ACT (“PLA”), OHIO REV. CODE § 2307.71, *ET SEQ.***

#### **(AGAINST ALL DEFENDANTS)**

273. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

274. This action is brought by Clinton County under the PLA to seek compensatory damages from Defendants for death, physical injury to person, emotional distress, or physical

damage to property. Defendants, individually, and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of the citizens of Clinton County or interferes with the comfortable enjoyment of life in violation of Ohio law.

275. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. The staggering rate of opioid use resulting from Defendants' marketing efforts and distribution history have caused harm to the community that includes, but is not limited to, the following:

- a. Upwards of 30% of all adults have used them. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- b. Children too have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Ohio teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. People who have never taken opioids also have suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- d. More broadly, opioid use and misuse have driven health care costs higher.
- e. Employers have lost the value of productive and healthy employees who suffered from adverse consequences from opioid use.
- f. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of

addicts to buy them. Then, Distributor Defendants failed to apprise anyone of the surge in opioid distribution until it was too late, even in light of the enormity of the pills going to small, finite geographic areas.

- g. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.
- h. The diversion of opioids into the secondary, criminal, market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on emergency services and law enforcement in Clinton County.
- i. All of this has caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.
- j. These harms have taxed the human, medical, public health, law enforcement, and financial resources of the State.
- k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is unreasonable as there is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

276. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

- a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the State and Clinton County, in particular.
- b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.
- c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.
- d. Rather than complying with federal law requiring mandatory reporting of huge, unexplained quantities of pills shipped to particular areas, Distributor Defendants continued to ship millions of opioids in geographic units where even minimal diligence would have indicated a problem, such as in Clinton County.

- e. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

277. Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Defendants' actions were also a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

278. The health and safety of the citizens of Clinton County, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the Clinton County's citizens and residents.

279. Defendants' conduct has affected and continues to affect a considerable number of people within Clinton County and across Ohio and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

## **COUNT TWO**

### **PUBLIC NUISANCE OHIO COMMON LAW**

#### **(AGAINST ALL DEFENDANTS)**

280. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

281. This action is brought by Clinton County under Ohio common law to seek damages and abate the public nuisance created by Defendants. This claim does not seek compensatory damages for death, physical injury to person, emotional distress, or physical damage to property.

282. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of citizens of Clinton County and across Ohio or interferes with the comfortable enjoyment of life in violation of Ohio law.

283. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. The staggering rate of opioid use resulting from Defendants' marketing efforts have caused harm to the community that includes, but is not limited to, the following:

- a. Upwards of 30% of all adults have used them. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- b. Children too have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Ohio teenagers; opioid use among teenagers is outpaced only by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Ohioans, including those in Clinton County, who have never taken opioids have also suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- d. More broadly, opioid use and misuse have driven health care costs higher.
- e. Employers have lost the value of productive and healthy employees who suffered from adverse consequences from opioid use.
- f. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for

opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

- g. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.
- h. The diversion of opioids into the secondary, criminal, market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on emergency services and law enforcement in Clinton County.
- i. All of this has caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.
- j. These harms have taxed the human, medical, public health, law enforcement, and financial resources of the County.
- k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

284. Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

- a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the County.
- b. Defendants' actions created and expanded the market for opioids, promoting their wide use for pain management.
- c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.
- d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.
- e. Defendants knew or should have known that distributing the number of opioids in the staggering numbers in which they entered Clinton County violated their duties as distributors and would have deleterious effects

when more pills were entering the County than could be used in a reasonable medical manner.

285. Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Moreover, Defendants' actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

286. The health and safety of the citizens of Clinton County, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the County's citizens and residents.

287. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

288. Defendants' conduct has affected and continues to affect a considerable number of people within Clinton County is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

289. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury, and each Defendant is jointly and severally liable for abating it.

### **COUNT THREE**

#### **FRAUDULENT MISREPRESENTATION AND OMISSION**

#### **(AGAINST ALL DEFENDANTS)**

290. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

291. Manufacturer Defendants made certain representations and/or omissions, which have been previously pled and are outlined below, regarding the nature, quality, and characteristics of the opioid pills that it manufactured. All Manufacturer and Distributor Defendants made false statements regarding their compliance with applicable laws, including, but not limited to, their duties to serve as a check on orders, to report suspect orders, and to prevent diversion of opioids.

292. At the time these representations and/or omissions were made, Defendants knew that the representations were false.

293. Even though Defendants knew that such representations were false, they failed to disclose and omitted any correction of what they knew were factual misrepresentations.

294. Even if Defendants did not know that the representations were false at the time they were made, they made the statements with reckless disregard of their truth and failed to correct such statements once learning of their inaccuracy.

295. Further, the following acts and practices constitute non-exhaustive examples (with more to be developed in discovery and proved at trial) of the fraudulent misrepresentations that Manufacturer Defendants have committed. Each example is substantiated through specific allegations relayed in the hundreds of factual allegations in the Complaint. As such, examples of the fraudulent misrepresentations include, but are not limited to, the following:

- Making any express or implied statement in connection with the marketing or advertisement of any product that is false, or has the capacity, tendency or effect of deceiving or misleading consumers; or omitting any material information such that the express or implied statement deceives or tends to deceive consumers.
- Making any representation, in connection with the marketing or advertising of a product, about research that has been performed, including, but not limited to, any representation that a product has been

clinically tested unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim.

- Making, in connection with the marketing or advertising of a product, any statements or representations concerning a product that materially contradict or conflict with any other statements or representations the Manufacturer Defendants made about such product and render such statements or representations misleading and/or deceptive.
- Making, or causing to be made, any written or oral claim that is false, misleading or deceptive.
- Representing that any product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.
- Representing that any product has any sponsorship, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.
- Making in a promotional context an express or implied representation, not approved or permitted for use in the labeling or under the FDCA, that a product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by competent and reliable scientific evidence, whether or not such express or implied representation is made by comparison with another drug or treatment, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, a quotation, or other reference.
- Presenting information from a study in a way that implies that the study represents larger or more general experience with a product than it actually does.
- Misleadingly presenting favorable information or conclusion(s) from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusion(s) for information that may be material to an HCP prescribing decision when presenting information about a clinical study regarding a product.
- Making, or causing to be made, any written or oral claim, directly or by promotional speakers, that is false, misleading, or deceptive regarding any FDA-approved product, including, but not limited to, any false, misleading, or deceptive claim when comparing the efficacy or safety of two products.

- Making any claim, directly or by promotional speakers, comparing the safety or efficacy of a product to another product when they claim is not supported by substantial evidence.
- Making any claim, directly or by promotional speakers, that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product labeling.

296. As alleged herein, each Manufacturer Defendant, at all times relevant to this Complaint made deceptive representations about the use of opioids to treat chronic, non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Manufacturer Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive. Similarly, each Distributor Defendant had a duty to disclose material facts but instead concealed facts. Each Distributor Defendant had a duty to serve as a monitor and to check the flow of opioids, but each instead made false representations or omissions in relation to that duty. All Defendants acted with the intent to mislead the Clinton County community, its citizens, and persons on whom the citizens and the County relied.

297. Defendant Purdue made, disseminated, or assisted in the creation or dissemination of false or misleading statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Ohio consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Exclusively disseminating misleading statements in education materials to Ohio hospital doctors and staff while purportedly educating them on new pain standards;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing; and
- Withholding from Ohio law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

298. Defendant Endo made and/or disseminated false or misleading statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing.

299. Defendant Janssen made and/or disseminated false and misleading deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-

cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-

cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing.

300. Defendant Cephalon made and/or disseminated false and misleading statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to Ohio prescribers through in-person

detailing and speakers bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing and speakers bureau events.

301. Defendant Actavis made and/or disseminated false and misleading statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing;
- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

302. These deceptive representations and concealments were reasonably calculated to deceive Clinton County and its citizens, were made with the intent to deceive Clinton County and its citizens, and did in fact deceive the Clinton County and its citizens.

303. As described more specifically above, Defendants' representations and concealments constitute a course of conduct that continues to this day.

304. As a direct and proximate cause of Defendants' deceptive conduct, Clinton County and its citizens have been injured in an amount to be determined at trial.

305. These false representations and concealments were intended to deceive Clinton County and physicians so that more opioids would be prescribed and did in fact deceive them.

306. But for these false representations and concealments of material fact, Clinton County and its agencies would not have incurred millions of dollars in additional costs and expenses necessary to abate the opioid health crisis.

307. As a direct and proximate cause of Manufacturer and Distributor Defendants' fraudulent conduct, Clinton County has been injured.

**COUNT FOUR**

**RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT  
18 U.S.C. § 1961, *ET SEQ.***

**(AGAINST ALL DEFENDANTS)**

308. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

309. This claim is brought by Clinton County against Defendants Purdue, Janssen, Cephalon, Endo, Actavis, AmerisourceBergen, Cardinal, and McKesson for actual damages, treble damages, and equitable relief under the Racketeer Influenced and Corrupt Organizations Act. *See* 18 U.S.C. § 1961, *et seq.*

310. As supported by the facts in this Complaint, Defendants violated RICO through the following:

- Conduct: Marketing, manufacturing, and distributing dangerous opioid pills in a manner that increased their usage in violation of a number of drug control laws which Defendants had a duty to follow.
- Enterprise: In order for their plan to succeed, Defendants necessarily worked together because opioids are distributed according to a closed system. Drug Manufacturers => Wholesale Distributors => Pharmacies => Consumers.
- Pattern: As alleged throughout this Complaint, Defendants were involved with the same organization, touting the same messages, and systematically ignoring the same laws to manufacture and ship opioid pills in numbers far exceeding medical need and to maximize profits. The allegations in this Complaint detail the repeated interaction and coordination, which will only be supplemented with the benefit of discovery.
- Racketeering Activity, i.e., the “predicate act:” Defendants’ racketeering activity includes mail fraud, wire fraud, and the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishment under any law of the United States.

311. Clinton County, acting by and through its Commissioners, is a “person” as defined in 18 U.S.C. § 1961(3) because it is an entity capable of holding a legal or beneficial interest in property. The County has standing to sue under RICO even if it is considered an indirect victim that has sustained indirect injury. *See Henry & Wright Corp. v. Auto. Press Corp.*, 924 F.2d 1058 (6th Cir. 1991) (table decision); *County of Oakland by Kuhn v. Detroit*, 784 F. Supp. 1275 (E.D. Mich. 1992).

312. Defendants operated their businesses in a manner that constitutes an “enterprise” for purposes of RICO in that they are engaged in an association by their conduct or else an enterprise of separate corporations, associations, or other legal entities. *See* 18 U.S.C. § 1961(4).

313. As set forth below and throughout the Complaint, Defendants engaged in a “pattern of racketeering activity” in that they engaged in at least two acts of racketeering activity within the applicable time period. *See* 18 U.S.C. § 1961(5).

314. Since the early 2000s, Defendants have engaged in a concerted effort to market opioid pills in a manner never before seen then ship more pills than were medically necessary into Clinton County, into Ohio, and across the United States. Defendants do not enjoy unfettered discretion to ply more and more pills to the public because they are registrants under the Controlled Substances Act. *See* 21 U.S.C. § 821, *et seq.* As a result, Defendants must comply with their obligations as registrants, including, but not limited to:

- obtaining an annual registration issued by the Attorney General;
- maintain effective controls against diversion of a particular controlled substance other than for legitimate medical, scientific, research, or industrial channels; and
- complying with applicable state and federal laws.

*See* 21 U.S.C. § 823(a).

315. In addition, Defendants' sales volumes must stay within applicable quotas set by the Drug Enforcement Agency, not to mention that registrants must possess internal checks that identify suspicious, often large, volumes of opioids ordered for reporting to the DEA.

316. The only means by which opioid pills can reach a consumer is through what is referred to as a "closed system." The CSA provides for substantial control by the Justice Department of drug abuse issues and in doing so created this registration system that makes any transaction outside the chain illegal. *See* 1970 U.S.C.C.A.N. 4566, 4569. Hence, a "closed system." The intent of this system is to prevent the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. *Id.* at 4571-72.

317. The closed system designed under the CSA specifically provided internal cross checks between registrants and quotas, which had as its purpose the intent of avoiding diversion. *See* Declaration of Joseph Rannazzisi, Deputy Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶ 8.

318. In seeking profits over their duties under the law, Defendants increased their sales and profit by amounts only to be achieved through coordination of effort. For example, Defendants committed all of the following:

- they marketed opioids in ways that increased the likelihood that they entered parts of the distribution chain in ways that they would be used for improper purposes under the CSA;
- they violated their duties under the CSA to maintain effective diversion controls;
- they failed to develop a system that would identify suspicious orders, or, in the alternative, decided to systematically disregard any such duty; and
- they failed to report suspicious orders to the DEA, or in the alternative, decided to systematically disregard any such duty.

319. Manufacturer Defendants and Distributor Defendants acted in concert and by association to distribute as many opioids as possible under the premise that the opioids were safe for chronic pain use, all the while disregarding federal and state regulations placed upon them as registrants. Instead of faithfully reporting under the closed system arrangement to help curb diversion, both Manufacturer Defendants and Distributor Defendants failed to fulfill these obligations and maximized their profits by distributing as many opioid pills as possible. And their profits support that their actions were successful. Defendants made profits that caused Clinton County and counties across Ohio damages.

320. Although more specific information is pleaded below and will be proved after discovery, common sense further supports the existence of an enterprise among Defendants. Absent coordination between all Defendants, the epidemic would have never happened. Had just one Manufacturer Defendant taken the firm position that opioid pills should not be used for chronic pain, this epidemic could have been prevented. Had just one Distributor Defendant questioned the millions of pills shipped to certain areas of the country, including Clinton County, the DEA would have had more information to further investigate the breakdown in the closed system. Instead, they all funded groups, sent KOLs, and remained silent in violation of their duties.

321. The association and enterprise between Defendants violates 18 U.S.C. § 1962(c) and entitles Clinton County to treble damages for its injuries under 18 U.S.C. § 1964(c).

322. Beginning its operations in 1876 under a previous name, the non-profit Healthcare Distribution Alliance (“HDA”) held its first meeting to “remedy the existing evils in the wholesale drug business, and enable merchants to carry on business on a more profitable basis.”

See <https://www.healthcaredistribution.org/about/hda-history>. The HDA first used this title in

2016 “to reflect the organization’s growing role as a convener of the supply chain both domestically and globally.” *Id.* The HDA is currently a non-profit formed under the laws of Washington, D.C.

323. From its headquarters in Arlington, Virginia, the HDA represents 34 distribution companies and 145 manufacturer companies. As members of HDA and as a legal entity defined under 18 U.S.C. § 1961(4), Defendants furthered their racketeering activity and thus supporting another RICO enterprise.

324. HDA itself can serve as a RICO enterprise because all of the Defendants are separate entities. Notably, HDA has members other than the Defendants. As such, HAD can serve as a RICO enterprise of Defendants.

#### **WHAT IS THE CONDUCT OF THE RICO ENTERPRISE?**

325. At all times relevant to the Complaint, Defendants’ conduct includes the control and furtherance of a RICO enterprise designed to market opioids in illegal and inaccurate ways, the failure to follow federal and state laws imposed upon the Defendants to encourage the avoidance of diversion, and the failure to report suspicious sales to the DEA, all the while bring massive profits to themselves.

326. Defendants furthered their RICO enterprise in numerous ways, which are identified below and which will be further identified through discovery and proved at trial:

- distributing deceptive, false, and inaccurate statements claiming that they installed and applied effective controls to safeguard against illegal diversion of dangerous opioid drugs;
- distributing deceptive, false, and inaccurate statements claiming that they complied with reporting requirements by reporting suspicious shipments of dangerous opioid pills to the DEA; and

- distributing deceptive, false, and misleading statements claiming that internal controls were designed sufficient to identify suspicious order in compliance with state and federal law.

327. Defendants knew or should have known that they were shipping suspicious orders. Had they been performing their duties under state and federal law, they would have reported such orders to the DEA.

328. Yet Defendants failed to stop suspicious orders, despite the fact that from 2008-2012 the DEA issued final decisions in 178 registrant actions involving Distributor Defendants. During that same period, The Office of Administrative Law Judges recommended decisions in 117 registrant actions. And these totals even include 76 actions involving orders to show cause, plus 41 actions for immediate suspension orders. All of these totals were for failure to report suspicious orders.<sup>59</sup>

329. Manufacturer Defendants worked with Distributor Defendants to effectuate the RICO enterprise. Manufacturer Defendants set out to increase demand followed by increased quotas so they could sell more opioids to derive more profit. In turn, Defendants turned a blind eye to their duties to report suspicious orders that surpass appropriate quotas or even common sense.

330. At the top, Defendants employed HDA and the PCF to influence the political process. As a result, laws changed in ways that favored the opioid industry.

331. Distributor Defendants' failure to report suspicious orders allowed the various quotas set by the DEA to remain high and even increase. This was because the DEA lacked sufficient data on any suspicious orders to make appropriate decisions.

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<sup>59</sup> See Evaluation and Inspections Div., Office of the Inspector Gen. U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registration Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

332. Defendants further influenced DEA quotas in the follow manners:

- Defendants engaged in coordinated lobbying efforts through the PCF;
- Distributor Defendants provided sales data to Manufacturer Defendants, including all prescriptions filled, which gave Manufacturer Defendants additional information by which to market opioid pills;
- Manufacturer Defendants joined HDA at the behest of Distributor Defendants, further coordinating inside its infrastructure;
- Distributor Defendants received rebate and chargebacks for orders of prescription opioids;
- through QuintilesIMS, Manufacturer Defendants received a “stream of data showing how individual doctors across the nation were prescribing opioids,”<sup>60</sup>
- Manufacturer Defendants used sales data it received from numerous sources to advise Distributor Defendants on focus areas for their sales and distribution;
- Distributor Defendants continued to fill suspicious orders without reporting them to Manufacturing Defendants, or, more significantly, the DEA, even despite warnings and decisions issued against them by the DEA; and
- Defendants failed to fully disclose information to the DEA so that it could perform its law enforcement purpose of stopping the proliferation of dangerous opioids.

333. Through their co-membership in the PCF, Manufacturing and Distribution Defendants contributed hundreds of millions of dollars in joint lobbying efforts aimed at governments at all levels. All were members of the PCF or associated via the HDA.

334. Through these lobbying efforts, Defendants jointly obtained favorable laws and administrative agency rulings that either allowed the further marketing and proliferation of

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<sup>60</sup> Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

dangerous opioid pills for chronic pain or attempt to diminish the enforcement capabilities of the DEA.

335. Defendants' lobbying efforts were successful in obtaining passage of the "Ensuring Patient Access and Effective Drug Enforcement Act," which prevented the DEA from suspending registrants pending investigation. They were also successful in slowing down or even preventing prosecutions for their actions.

336. Defendants used rebates and chargebacks to offer incentives to ship more opioid pills. Through such payments, Defendants coordinated target focus areas for the sales of opioids based upon demand and consumption statistics.

337. Despite the DEA's intentions to help Distributor Defendants by encouraging the use of "know your customer" questionnaires, this did little to help them further identify suspicious orders. Instead, the questionnaires were tools used to advise where to focus shipments based upon demand and consumption statistics.

338. By acting in concert, Defendants' common conduct to misrepresent safe uses of opioids and by failing to report suspicious orders achieved Defendants' goal—increase the sale of their product to make more profits, despite engaging in illegal activity.

#### **WHAT IS THE RICO ENTERPRISE?**

339. As set forth above, the manufacture and distribution of opioid pills occurs in a closed system designed by Congress to help prevent illegal diversion. But it requires all registrants to diligently act to monitor, identify, and report suspicious orders, which has not occurred.

340. Despite being issued multiple reminder letters from the DEA in 2006 and 2007, Distributor Defendants still failed to adequately monitor, identify, and report suspicious orders.

341. The CSA directed the DEA to determine quotas for opioid pill distribution, which was intended to reduce or eliminate illegal diversion. Numerous factors are involved in setting the quotas including by way of example, net disposal by manufacturers, national trends, and currently accepted medical practice.

342. Manufacturer Defendants are prohibited by federal law to manufacture opioids which are not expressly authorized by their registration and by a quota or in excess of a quota assigned to the manufacturer. *See* 21 U.S.C. § 842(b).

343. The RICO enterprise functioned to illegally inflate demand, thus creating higher sales volume for opioids than previously experienced. Then, Defendants turned a blind eye to their duties to report suspicious orders. All of this allowed for an artificial, enterprise-driven increase in the quotas. Manufacturing and distributing more opioids meant more profits in Clinton County and across the United States.

344. The RICO enterprise began in the mid-2000s, when Manufacturer Defendants drove the demand for opioid pills up and Distributor Defendants failed to report suspicious orders. Since that time, this enterprise has caused the health epidemic we face in an uninterrupted fashion.

345. Based upon Ohio Department of Health statistics, progress of the opioid pill proliferation has finally been curbed, although massive damages have already been incurred and will continue to be incurred.

346. At all times relevant in the Complaint, the RICO enterprise had a separate and distinct existence from each Defendant.

347. At all times relevant in the Complaint, the RICO enterprise had a separate and distinct appearance from the pattern of racketeering in which Defendants engaged.

348. At all times relevant in the Complaint, the RICO enterprise was ongoing and continuing in its organization of level entities.

349. At all times relevant in the Complaint, Defendants had personal relationships that helped further the RICO enterprise.

350. The RICO enterprise survived long enough to achieve its goals and purposes, functioning as a continuing unit.

351. The whole purpose of the RICO enterprise was to sell more opioid pills. Despite their sometimes legitimate, prescribed uses, Defendants illegally marketed the drugs and manipulated physicians by misrepresenting the risks, failing to set up effective controls for rooting out suspicious orders, or outright failing to report suspicious orders, all of which involved racketeering activity as part of the RICO enterprise. Ultimately by manipulating data and even the DEA, the RICO enterprise illegally achieved the goal of placing more opioids in the market for public consumption for the gain of Defendants.

352. The RICO enterprise involved interstate and foreign commerce through its activities across state lines, especially given that the Defendants hail from numerous different states. Nonetheless, messages, pills, and money transferred across the country between Defendants.

353. But for the interpersonal relationships between Defendants and the entities they arranged to do their bidding (*e.g.*, PCF or KOLs), the RICO enterprise would not have succeeded.

354. As alleged throughout the Complaint, numerous links exist between Defendants through lobbying, trade organizations, and their own coordination designed to achieve their

objectives. As such, Defendants actively participated in the actions set forth as part of their RICO enterprise.

355. Defendants used the PCF to shape federal and state policies regarding opioids, despite ostensibly being merely a coalition of drug makers.

356. The Center for Public Integrity and The Associated Press recently obtained and reported on documents showing the extent to which Defendants used the PCF to enact their policies and support the RICO enterprise.<sup>61</sup> In fact, the documents revealed that the PCF spent \$743 million in lobbying for Defendants' policies all across the county.

357. Through a consistent array of in-person and typically monthly meetings, the interpersonal relationships between Defendants were maintained and thus shaped opioid policy across the country. These meetings were in furtherance of the RICO enterprise.

358. The same kinds of interpersonal relationships arose from Defendants' membership and coordination through HDA to shape opioid policy. These interpersonal relationships that arose from HDA membership and participation, often at the executive level, were in further of the RICO enterprise.

359. HDA engaged Defendants in various councils, tasks forces, working groups, or committees to advance their interpersonal relationships alleged as part of the RICO enterprise.

360. Through these committees, Defendants, and their representatives taking part in HDA, further honed the policies and conduct as part of the RICO enterprise. Instead of needing

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<sup>61</sup> Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01am), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

to informally organize, HDA provided Defendants business and leadership meetings that brought together executives and policy-makers that resulted in furthering the RICO enterprise.

361. As described by Senator McCaskill in letters sent in March, July, and September 2017, Manufacturer Defendants would pay Distributor Defendants rebates or chargebacks on opioid sales. These contractual relationships furthered the interpersonal relationships that were used to maintain and further the RICO enterprise.

362. Further, because Manufacturer Defendants paid these rebates or chargebacks, Distributor Defendants provided crucial information for Manufacturer Defendants to further assist Distributor Defendant with selling more opioids.

363. Through all of these connections, Defendants operated an effective RICO enterprise by coordinating in several organizations on multiple fronts, all the while drastically affecting opioid policy and turning a blind eye to state and federal law regulating drug distribution. Defendants overlap with their presence in all of these organizations, furthering the RICO enterprise's purposes and goals.

#### **WHAT IS THE PATTERN OF RACKETEERING ACTIVITY?**

364. The RICO enterprise consists of conduct by Defendants that consists of racketeering activity, which includes federal offenses related to mail fraud, wire fraud, and the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the CSA), punishable by law in the United States.

#### **Defendants committed wire fraud and mail fraud**

365. Defendants committed mail fraud and wire fraud in violation of federal law. *See* 18 U.S.C. § 1341 and 18 U.S.C. § 1343, respectively. They achieved and/or sought to employ a

plan that involved racketeering activity to commit fraud on federal and state regulators, the medical community, and the public.

366. Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity within the past 10 years based upon their mail fraud and wire fraud. These multiple acts were related to each other, posed a threat to continue, and meet the element of a “pattern of racketeering activity” under RICO. Such actions were made possible by use of facilities, services, distribution channels, and employees of Defendants by attempting to defraud using the mail, telephone, and internet to transmit mailings and wires in interstate or foreign commerce.

367. At Defendants’ direction or personal use, thousands of interstate mail and wire communications supported the RICO enterprise through similar misrepresentations, concealments, and material omissions regarding their compliance with state and federal law mandating their monitoring and reporting of suspicious orders, all the while with the intent of carrying out the illegal scheme to sell opioids at rates far exceeding any reasonable medical use.

368. Defendants’ RICO enterprise involved racketeering activity in which it employed false or fraudulent pretenses, representations, promises, or omissions of material facts. These acts number in the thousands, involving intentional and knowing behavior with the specific intent to achieve their objectives—drive profit to Defendants.

369. The predicate acts of racketeering under 18 U.S.C. § 1961(1) include, but are not limited to, wire fraud and mail fraud. Each Defendant violated 18 U.S.C. §§ 1341 and 1343 by sending or receiving, or by causing to be sent and/or received, materials via wire or commercial interstate carriers for the purpose of executing their plan to market and sell an increased amount of opioid pills based upon fraud and false representations and/or omissions.

370. Defendants used wires and mail to transmit or ship a wide range of items used to support the RICO enterprise, including, but not limited to:

- opioid pills;
- documents between Defendants that facilitated the marketing, purchase, and unlawful distribution of opioids;
- communications that supported and/or facilitated Defendants' registrations, requests for higher quotas, and reports for the DEA;
- shipping documents between Manufacturing Defendants, Distributor Defendants, and anyone else in the closed system;
- payments between parties within the closed system;
- rebate and chargebacks from Manufacturer Defendants to Distributor Defendants;
- payments, communications, and other documents transferred in and amongst Defendants and groups like HDA, PCF, and KOLs; and
- innumerable electronic communications sent in an effort to facilitate and advance the RICO enterprise.

371. Each and every Manufacturer Defendant manufactures opioids that, upon information and belief, were distributed by Distributor Defendants in Clinton County and to its citizens.

372. To the extent that precise dates and communications are necessary, Defendants' RICO enterprise was conducted in secret and outside the public view. As alleged throughout this Complaint, the predicate acts nonetheless occurred. All of the items in the preceding Paragraphs will be found throughout discovery and used at trial to prove Clinton County's claims.

373. Defendants acted in concert in committing wire fraud and mail fraud, which means that they violated 18 U.S.C. § 1962(c). While others may have been involved, their

identities and precise involvement are currently unknown and will be learned further throughout the course of discovery.

374. Defendants agreed to similar goals and means of obtaining them, which made their RICO enterprise even more effective. As such, each Defendant agreed to the overall objectives and means of obtaining them.

375. The overall objective was to increase revenues for each Defendant, which is documented through statistics for the relevant time period. The RICO enterprise made Defendants even more profitable than before it began.

376. The RICO enterprise began as alleged in the Complaint and will continue until this Court enjoins any further coordinated actions between Defendants in furtherance of the enterprise.

377. Clinton County seeks damages that are neither remote nor unexpected. In the absence of responsible, accurate marketing and adequate reporting of suspicious orders, there was nothing stopping the illegal flow of opioids into Clinton County and across Ohio at a rate that exceeds any reasonable medical use.

378. The RICO enterprise is ongoing, so the last racketeering activity occurred within the applicable time period for RICO.

**Defendants committed felonies related to manufacture, sale, and dealing in controlled substances**

379. Defendants conducted and participated in the conduct that constitutes the RICO enterprise through a pattern of racketeering activity under 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under United States law.

380. Defendants committed crimes punishable as felonies, including, but not limited to, knowingly or intentionally furnishing false or fraudulent information in, or omitting material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. *See* 21 U.S.C. § 483(a)(4).

381. As registrants, Defendants were required to maintain adequate controls to safeguard against diversion and report suspicious orders. In violation of federal law, Defendants failed to report suspicious orders and/or provided false information concerning orders and/or omitted information about orders that allowed diversion of opioid pills in the open market, which inured to the Defendants' benefit as part of their RICO enterprise.

382. Several examples support Defendants' various failures to adequately monitor opioid shipments, including, but not limited to:

- on April 23, 2015, McKesson announced a settlement with the DEA and DOJ in which it admitted to violating the CSA and agreeing to pay a \$150 million fine, in addition to some suspensions of various DEA registrations;<sup>62</sup> and
- in 2016, the Los Angeles Times reported Purdue's failure to shut off the supply of Oxycontin after over a million pills went to a provider, despite tracking it and subsequently failing to report the provider to the authorities.<sup>63</sup>

383. These examples, and more to be uncovered through discovery, show the pattern and practices of willfully and intentionally omitting to report suspicious opioid orders. Further

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<sup>62</sup> McKesson, *McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims*, About McKesson/Newsroom/Press Releases (January 17, 2017), <http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-dog-and-dea-to-resolve-past-claims/>.

<sup>63</sup> Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times (July 10, 2016), <http://latimes.com/projects/la-me-oxycontin-part2/>.

supporting such a conclusion are the enforcement actions available in the public record against Distributor Defendants.

384. Despite a duty to maintain adequate monitoring, detection, and reporting of suspicious orders, Defendants systematically failed to identify and report such suspicious orders to the DEA.

385. The RICO enterprise began as alleged in the Complaint and will continue until this Court enjoins any further coordinated actions between Defendants in furtherance of the enterprise.

386. Clinton County seeks damages that are neither remote nor unexpected. In the absence of responsible, accurate, marketing and adequate reporting of suspicious orders, there was nothing stopping the illegal flow of opioids into Clinton County and across Ohio at a rate that exceeds any reasonable medical use.

387. The RICO enterprise is ongoing, so the last racketeering activity occurred within the applicable time period for RICO.

**WHAT ARE THE DAMAGES FROM THE RICO ENTERPRISE?**

388. Clinton County has faced and is facing injury to the County's funds and Clinton County citizens that is directly and proximately caused by the RICO enterprise's violations of the law.

389. Clinton County and its citizens' injuries include, but are not limited to, the increased cost of law enforcement, incarceration, treatment, and foster care.

390. No better Plaintiff exists to recover the damages that Clinton County seeks for itself and its citizens.

391. Clinton County seeks and is entitled to any and all equitable relief allowed by law, injunctive relief, as well as monetary relief for actual and treble damages. Clinton County is also entitled to its attorney's fees and costs, plus pre- and post-judgment interest.

**COUNT FIVE**

**OHIO CORRUPT PRACTICES ACT ("OCPA")  
OHIO REV. CODE § 2923.31, *ET SEQ.***

**(AGAINST PURDUE, JANSSEN, CEPHALON, AND ENDO)**

392. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs<sup>64</sup> of this Complaint as though fully alleged herein.

393. This claim is brought by Clinton County against Defendants Purdue, Janssen, Cephalon, and Endo for actual damages, treble damages, and equitable relief under Ohio Rev. Code § 2923.34 for violations of Ohio Rev. Code § 2923.31, *et seq.*, and, throughout this Cause of Action only, Defendants refers only to these entities.

394. The Defendants are "persons" within the meaning of Ohio Rev. Code § 2923.31(G) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of Ohio Rev. Code § 2923.31.

395. Clinton County is a "person," as that term is defined in Ohio Rev. Code § 2923.31, who was injured in its business or property as a result of Defendants' wrongful conduct. Clinton County includes all of its public offices and departments, such as the Sheriff's Office and Department of Job and Family Services, that have incurred additional costs and expenses based upon Defendants' actions.

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<sup>64</sup> Rather than repeat all the allegations throughout, Clinton County specifically pleads that the allegations in Count Five concerning RICO apply to Clinton County's claims under the Ohio Corrupt Practices Act.

**The Opioids Marketing Enterprise**

396. Defendants formed an association-in-fact enterprise – sometimes referred to in this Complaint as the Opioids Marketing Enterprise. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; (b) the Front Groups, including their employees and agents; and (c) the KOLs.

397. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to ensure the prescription of opioids for chronic pain.

398. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, Clinton County, and its citizens, the risks and benefits of using opioids for chronic pain. The Opioids Marketing Enterprise concealed from the public, Clinton County, and its citizens, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

399. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups, and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes

of implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

400. At all relevant times, Front Groups were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of Clinton County and its citizens. But for the Opioids Marketing Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

401. At all relevant times, KOLs were aware of Defendants' conduct, acted as knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of Clinton County and its citizens. But for the Opioids Marketing Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

402. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged Clinton County and throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations,

terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

403. The Front Groups and KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity, which includes multiple instances of mail fraud, and multiple instances of wire fraud, they knowingly made material misstatements or omissions to Clinton County physicians, its citizens, the people across Ohio and the general public in furtherance of the fraudulent scheme, including that:

- a. it was rare, or there was a low risk, that Defendants' opioids could lead to addiction;<sup>65</sup>
- b. the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;<sup>66</sup>
- c. opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult;<sup>67</sup>
- d. doctors could increase opioid dosages indefinitely without added risk;<sup>68</sup>
- e. long-term opioid use improved patients' function and quality of life;<sup>69</sup>

<sup>65</sup> American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

<sup>66</sup> National Initiative on Pain Control 2009 CME program, *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia* (sponsored by Endo).

<sup>67</sup> American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

<sup>68</sup> American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); Endo pamphlet edited by KOL: *Understanding Your Pain: Taking Oral Opioid Analgesics*; American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

<sup>69</sup> *Responsible Opioid Prescribing* (sponsored by Endo, Cephalon and Purdue) (remains for sale online); American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); CME entitled *Persistent Pain in the Older Patient* (sponsored by Endo).

- f. Purdue's OxyContin provided 12 hours of continuous pain relief;<sup>70</sup> and
- g. the extent to which the Opioids Marketing Scheme caused the State and Ohio consumers to pay for excessive opioid prescriptions, and to incur costs associated with abating the opioid epidemic caused by the Enterprise.

404. Defendants alone could not have accomplished the purpose of the Opioids Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as “neutral” and more “scientific” than Defendants themselves. Without these misrepresentations, the Opioids Marketing Enterprise could not have achieved its common purpose.

405. The effects of the Opioids Marketing Enterprise's scheme are still in place – *i.e.*, the opioids continue to be prescribed and used for chronic pain throughout Clinton County and across Ohio, and the epidemic continues to consume the resources of Clinton County's health care and law enforcement systems.

406. The foregoing evidences that Defendants, the Front Groups, and the KOLs were each willing participants in the Opioids Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

407. From approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation or management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of

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<sup>70</sup> American Pain Foundation.

independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

- b. Defendants selected, cultivated, promoted, and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;
- c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;
- e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- g. Defendants developed and disseminated pro-opioid treatment guidelines;
- h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;
- i. Defendants concealed their relationship to and control of Front Groups and KOLs from the State and the public at large; and
- j. Defendants intended that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

408. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to PBMs and payments to KOLs to ensure the representations made were consistent with Defendants' messaging nationwide, throughout Ohio, and in Clinton County. Front Groups were dependent on Defendants for their financial structure, and KOLs were professionally dependent on Defendants for the development and promotion of their careers.

409. The Front Groups also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;
- b. The Front Groups distribute through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and
- c. The Front Groups concealed their connections to Defendants.

410. The KOLs also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;
- b. The KOLs distributed through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and
- c. The KOLs concealed their connections to and sponsorship by Defendants.

411. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure additional payment for prescriptions of Defendants' opioids by Ohio patients and those in Clinton County, ultimately to the detriment of Clinton County and its citizens. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

**Pattern of Racketeering Activity**

412. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering activity as defined in Ohio Rev. Code §

2923.31(I)(2), which constitutes Corrupt Activity under Ohio Rev. Code § 2923.31(I)(1). The pattern of racketeering activity by the Opioids Marketing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioids Marketing Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constituted a pattern of racketeering activity, through which Defendants, the Front Groups, and the KOLs defrauded and intended to defraud Clinton County, its citizens, and other intended victims in creating Ohio's current opioid health crisis.

413. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Clinton County and its citizens. Defendants, the Front Groups, and the KOLs calculated and intentionally crafted the opioids marketing scheme to ensure their own profits remained high, without regard to the effect such behavior had on Clinton County and its citizens. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

414. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to Clinton County, its citizens, and all others across Ohio, Defendants, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

415. The racketeering activities of Defendants, the Front Groups, and the KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to

deceive Clinton County and its citizens. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Clinton County and its citizens. Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Opioids Marketing Enterprise.

416. The pattern of racketeering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

417. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

418. Many of the precise dates of the Opioids Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records of Defendants, the Front Groups, and the KOLs. Indeed, an essential part of the successful operation of the Opioids Marketing Enterprise alleged herein depended upon secrecy. However, Clinton County can generally describe the occasions on which the predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme, and do so below.

419. Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, including, *inter alia*:

- a. Marketing materials about Defendants' opioids, and their risks and benefits, which Defendants sent to health care providers located across the country and the State;

- b. Written representations and telephone calls between Defendants and Front Groups regarding representations about Defendants' opioids, or the use of opioids for chronic pain generally;
- c. Written representations and telephone calls between Defendants and KOLs regarding Defendants' opioids, or the use of opioids for chronic pain generally;
- d. Hundreds of e-mails between Defendants and the Front Groups agreeing to or effectuating the implementation of the opioids marketing scheme;
- e. Hundreds of e-mails between Defendants and KOLs agreeing to or effectuating the implementation of the opioids marketing scheme;
- f. Hundreds of communications between the Front Groups and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioids marketing scheme;
- g. Hundreds of communications between the KOLs and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioids marketing scheme;
- h. Written and oral communications directed to State agencies and private insurers throughout the State that fraudulently misrepresented the risks of benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities – the wrongful proceeds of the scheme.

420. In addition to the above-referenced predicate acts, it was foreseeable to Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

#### **Damages Caused by Defendants' Fraud**

421. Defendants' violations of law and their pattern of racketeering activity have caused Clinton County and its citizens damages based upon the increased costs of, by way of example, law enforcement and foster care stemming as a direct and proximate cause from the increase in opioid addiction fueled by Defendants' actions alleged in this Complaint.

422. Clinton County's injuries were proximately caused by Defendants' racketeering activity. But for the misstatements made by Defendants, the Front Groups, and the KOLs combined with the scheme employed by the Opioids Marketing Enterprise, Clinton County would not have additional expenses stemming from the opioid health crisis.

423. Clinton County's injuries were directly caused by Defendants' racketeering activity. Although the misstatements made by the Front Groups and the KOLs in furtherance of the Opioids Marketing Enterprise were directed primarily to health care providers, those providers did not have to make payments for opioids prescribed for chronic pain nor are they responsible for the increase law enforcement and foster care costs that have resulted. Therefore, Ohio health care providers did not suffer the same injuries alleged in this Complaint.

424. Clinton County and its citizens were most directly harmed by the fraud, and there is no other Plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Defendants' fraudulent scheme as they pertain to damages associated with Clinton County.

425. By virtue of these violations of Ohio Rev. Code § 2923.34, Defendants are liable to Clinton County for three times the damages that Clinton County has sustained, plus the cost of this suit, including reasonable attorneys' fees.

**COUNT SIX**

**INJURY THROUGH CRIMINAL ACTS  
OHIO REVISED CODE § 2307.60**

**(AGAINST DISTRIBUTOR DEFENDANTS)**

426. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

427. Section 2307.60(A)(1) of the Ohio Revised Code provides that anyone injured in person or property by a criminal act may recover full damages in a civil action.

428. Distributor Defendants' practices, as described in the Complaint, violated and Ohio Revised Code § 2925.02(A) (corrupting another with drugs) and Ohio Revised Code § 2925.03(A) (trafficking in drugs). Additional criminal acts are set forth above, particularly in Count Four.

429. When Distributor Defendants violated these Ohio Revised Code provisions alleged above, they caused damage to Clinton County and its citizens.

430. As a result, Clinton County seeks relief from all damages resulting from Distributor Defendants' criminal acts in violation of the Ohio Revised Code.

### **COUNT SEVEN**

#### **NEGLIGENCE AND NEGLIGENT MISREPRESENTATION**

##### **(AGAINST ALL DEFENDANTS)**

431. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

432. Defendants acted negligently based upon the allegations in this Complaint, including, but not limited to, representations from Manufacturer Defendants regarding the character, nature, and quality of opioid pills, and representations from Distributor Defendants that they complied with the law when they actually failed to report immense amounts of opioid pill distribution for particular geographic areas, including Clinton County.

433. Manufacturer Defendants owed a duty to Clinton County and its citizens to make representations regarding opioid pills in such a way that would not harm people.

434. Distributor Defendants owed a duty to Clinton County and its citizens to follow the law and report suspicious shipments of opioid pills that exceeded the reasonable levels for particular geographic areas, including Clinton County.

435. If either Manufacturer Defendants or Distributor Defendants acted with the requisite prudence when dealing with controlled substances such as the opioid pills involved here, each would have anticipated the health epidemic that they created because such resulting harm was reasonably foreseeable.

436. Law enforcement repeatedly warned and even fined Distributor Defendants such that they could not have been unaware of the health crisis resulting from their illegal conduct.

437. Discovery will reveal additional information from Defendants regarding the representations made and internal data regarding distribution to support Clinton County's allegations regarding negligence and/or negligent misrepresentation.

438. As a direct and proximate cause of Defendants' negligence, Clinton County and its citizens have sustained foreseeable damages.

## **COUNT EIGHT**

### **CIVIL CONSPIRACY**

#### **(AGAINST ALL DEFENDANTS)**

439. Clinton County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

440. As alleged in this Complaint, Manufacturer Defendants and Distributor Defendants engaged in a civil conspiracy that resulted in the current health epidemic facing Clinton County and Ohio regarding opioids.

441. As the Ohio Supreme Court has determined, a civil conspiracy has been defined as “a malicious combination of two or more persons to injure another in person or property, in a way not competent for one alone, resulting in actual damages.” *Kenty v. Transamerica Premium, Inc.*, 650 N.E.2d 863, paragraph 2 of syllabus (Ohio 1995).

442. Defendants acted in concert to maliciously create the opioid health epidemic by misrepresenting medical data regarding the dangers of opioid pills, failing to report shipments of pills far exceeding the rational medical need for an area, and all other ways alleged throughout this Complaint.

443. Both Manufacturer Defendants and Distributor Defendants acted in concert based upon the fact that the opioid distribution system is a closed network. Had one or the other groups of Defendants failed to engage in the conspiracy, it would not have been successful.

444. Clinton County and its citizens have incurred actual damages as a proximate result of Defendants’ actions related to opioid pills.

445. Consequently, Clinton County seeks compensation from all Defendants for the damages resulting from their civil conspiracy, excluding personal injury and wrongful death.

## **VII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, Clinton County, respectfully prays:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of State statutory and common law and that the Court enter a judgment declaring them to be so;

B. That Manufacturer Defendants be enjoined from – directly or indirectly through KOLs, Front Groups, or other third parties – continuing to misrepresent the risks and benefits of the use of opioids for chronic pain and from continuing to violate Ohio law;

C. That Distributor Defendants be found in violation of and ordered to follow the law with regard to reporting requirements for the shipping of opioids;

D. That Plaintiff recover all measures of damages allowable under the state statutes identified herein and the common law, and that judgment be entered against Defendants in favor of Plaintiff;

E. That Plaintiff receive an award of civil penalties for Defendants' fraudulent misrepresentation;

F. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law;

G. That Defendants be ordered to abate the public nuisance that they created in violation of Ohio common law;

H. That Defendants be ordered to pay punitive and treble damages as provided by law; and

I. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

DATED this 20th Day of December 2017.

**JURY DEMAND ENDORSEMENT**

Plaintiff, Clinton County Board of Commissioners, demands a trial by jury on all claims to the maximum number of jurors permitted by law.

/s/Mark H. Troutman  
Mark H. Troutman (0076390)

Respectfully submitted,

/s/Mark H. Troutman  
Mark H. Troutman (0076390), Trial Attorney  
Shawn Judge (0069493)  
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